S. HRG. 103-252

CHILD IMMUNIZATION INITIATIVE

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH
FOR FAMILIES AND THE UNINSURED

OF THE

COMMITTEE ON FINANCE
UNITED STATES SENATE

ONE HUNDRED THIRD CONGRESS

FIRST SESSION

ON

S. 733

MAY 6, 1993

Printed for the use of the Committee on Finance

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CHILD IMMUNIZATION INITIATIVE

THURSDAY, MAY 6, 1993

U.S. SENATE,
SUBCOMMITTEE ON HEALTH FOR FAMILIES
AND THE UNINSURED,
COMMITTEE ON FINANCE,
Washington, DC.

The hearing was convened, pursuant to notice, at 2:40 p.m., in room SD–215, Dirksen Senate Office Building, Hon. Donald W. Riegle, Jr. (chairman of the subcommittee) presiding.

Also present: Senators Bradley, Rockefeller, Danforth, and Durenberger.

[The press release announcing the hearing follows:]

[Press Release No. H–18, May 3, 1993]

FINANCE SUBCOMMITTEE ON HEALTH TO HOLD HEARING ON COMPREHENSIVE CHILD HEALTH IMMUNIZATION ACT

WASHINGTON, DC.—Senator Donald W. Riegle (D–MI), Chairman of the Committee on Finance Subcommittee on Health for Families and the Uninsured, announced today that the subcommittee will hold hearings on the administration's child immunization initiative.

The hearing is scheduled for *2:15 p.m. on Thursday, May 6, 1993,* and will be held in room SD–215 of the Dirksen Senate Office Building.

In announcing the hearing, Senator Riegle stated: "Too many of our pre-school children are not receiving their full set of vaccinations at the appropriate time for diseases like measles, polio, rubella, and mumps. We need a comprehensive plan to make sure every child is immunized by age 2."

"This hearing will focus on President Clinton's child immunization initiative. On April 1, I introduced S. 733, which has been referred to the Finance Committee and establishes a central bulk purchasing program for all vaccines, restores the excise tax for the injury compensation trust fund which expired in October 1992, and makes improvements to the Medicaid program."

OPENING STATEMENT OF HON. DONALD W. RIEGLE, JR., A U.S. SENATOR FROM MICHIGAN, CHAIRMAN OF THE SUBCOMMITTEE

Senator RIEGLE. The committee will come to order. Let me welcome all those in attendance. I apologize for the late start. We just had a vote on the Senate floor which required us being there. We are ready to go. Senator Durenberger is here and others will come.

I want to say for the record that Senator Pryor very much wanted to attend, but he was not able to do so. He is on his way to Arkansas today and he has left his statement. Without objection, I will make it part of the record.

[The prepared statement of Senator Pryor appears in the appendix.]

Senator RIEGLE. I want to also indicate that Senator Kennedy, while he does not serve on this committee is keenly interested in this issue and, of course, is the Chairman of the Labor Committee. So he will be coming by later to sit in on this hearing that we are having.

Today's hearing of the Finance Subcommittee is going to focus on President Clinton's efforts to immunize all the children in America by the age of two. S. 732 and S. 733, which are bills that Senator Kennedy and I introduced, along with six other Senators. Together the two bills represent President Clinton's immunization initiative. I am very pleased, as I said, that Senator Kennedy will be along later to take part in this important hearing.

The bill S. 733, which has been referred here to the Finance Committee and is the specific focus of this hearing, establishes a central bulk purchasing program for all vaccines, restores the excise tax for the Injury Compensation Trust Fund, which expired in October of 1992, and makes improvements to the Medicaid program.

Just for the record, it's important to note that the United States ranks 103 among 130 nations of all levels of development in immunizing our 1-year-olds. We are only managing to immunize 48 percent of our 1-year-olds, while countries like Cuba have achieved a 93-percent rate, Bulgaria a 99-percent rate, Honduras a 76-percent rate, and so it goes among many, many other countries.

In 1992, over one-third of Michigan's children, or an approximate 160,000 children, did not receive their full set of vaccinations that they should have had by their second birthday.

We will have a family from Michigan here a little bit later to speak about that problem.

The problem of low immunization rates actually affects all children—70 percent of 2-year-olds who are not immunized have family incomes that are above the poverty line. So we are finding this is not just a situation that affects the families in poverty circumstances.

The Clinton administration under Secretary Shalala's leadership and direction is considering revisions to their plan to address concerns about the universal purchase program. In the House, the relevant committees plan to include a revised version in their budget reconciliation bill. Secretary Shalala will discuss that today, and it is in that vein we are holding this hearing.

We want to solicit the views of all interested parties and continue working to improve the bill that we introduced on the 1st of April.

Democrats and Republicans agree on many aspects of what must be done in a comprehensive plan. These include creating an immunization registry of medical records, rebuilding our public health system of clinics as the President proposed wisely in the stimulus package, reinstating the excise tax and other needed changes to the injury compensation program and making needed improvements to Medicaid.

Senators Durenberger, Danforth, and Kassebaum introduced legislation earlier this week, and I am looking forward to working with them. I believe we can develop a proposal to make sure all

children are immunized, but it has to address all the barriers and cost, of course, is one of those important barriers.

Our plan is comprehensive and it addresses all the barriers in our current system. I note that it is in this context that a Federal purchase program is being proposed. One of the central problems is that many children who go to private physicians are being referred to public clinics because of the high cost of vaccines.

Costs vary from $120 for a full set of vaccines in the public sector to over $240 in the private. And, in fact, it can be a good bit higher than that. These referrals result in missed opportunities to vaccinate pre-schoolers.

As I said, we will hear from a mother today from Lansing, MI, Ms. Heidi Snarr, about the problems she has experienced. Michigan, as a State, produces and distributes the DTP vaccine free to all providers. And there has been an increase in private doctors providing DTP as a result of this.

The comprehensive solution which includes a version of a bulk purchase program is needed to keep immunization services delivered in private offices, which is where most children get their regular health care.

The new proposal would target the children most at risk, including those who have no private coverage and those on Medicaid. I understand the concern that setting too low a price could discourage vaccine research and development. That is why we specified that the negotiated price would include cost for research and development as well as a fair rate of return.

We also require multiple contracts when there are multiple producers of a vaccine. This should stimulate competition and make sure there is an adequate supply of vaccines. In fact, the State of Michigan has indicated that it would like to bid for these government contracts for DTP.

So today we will be hearing from many distinguished witnesses. I want to also include in the record at this point a list of 80 supporters of the Comprehensive Child Immunization Act and I have that list here for the record.

[The list appears in the appendix.]

Senator RIEGLE. Let me now call on the members of the committee that are here; and after I have done that I want to call on Senator Kennedy.

Senator Durenberger?

Senator DURENBERGER. Mr. Chairman, I have a statement that I would like to submit with respect to the Secretary and the other witnesses that I would ask to be made a part of the record.

Senator RIEGLE. Without objection, so ordered.

[The prepared statement of Senator Durenberger appears in the appendix.]

OPENING STATEMENT OF HON. DAVE DURENBERGER, A U.S. SENATOR FOR MINNESOTA

Senator DURENBERGER. I would just summarize about our bill. You know what our bill is and I think you will have an opportunity to discuss it in the course of the questioning. We will ask questions relative to the various approaches.

But you made reference to Cuba, and I think that is appropriate. I have been to Cuba. What strikes me about a country like that is they do make a commitment to children, and they make a commitment to health, they make a commitment to education, and they make a commitment to support. They take great pride in the fact that kids are not washing windows with their hands out at intersections, that women nor men are not prostituting themselves for money.

The Cuban society is different from the one in which we live in this country. I think if there is a way to summarize some of the differences in our approaches here, that we have to bring some kind of responsibility for the children in America back to the communities of America, however we may define that.

Immunization is an appropriate part of community commitment and personal commitment—personal and public health. But there is a much larger commitment that we need to make in this country. I think the closer we start to community in doing that—you have mentioned the State of Michigan.

I can brag up the State of Minnesota. They do not support the administration approach of large sums of money that sort of federalize the vaccine program in this country. They support a much more flexible kind of a program in which communities will determine the most appropriate way to provide for moms and kids, what exactly those moms and kids need, and the Federal Government will provide the financial support along with State and local governments to accomplish that.

Senator RIEGLE. Thank you, Senator Durenberger.

Senator Bradley?

OPENING STATEMENT OF HON. BILL BRADLEY, A U.S. SENATOR FROM NEW JERSEY

Senator BRADLEY. Thank you very much, Senator Riegle. Today I know that we are going to hear from a very significant cross-section of child advocates from families and from providers, vaccine manufacturers, from the Children's Defense Fund and from our administration.

I would like to thank Secretary Shalala for unflagging efforts on behalf of children and for being here today to share with us her views on this issue.

I think the challenge is pretty clear. What must we do to assure that all children are fully immunized on time, and how can we get the public and private sector engaged in this quest?

Since the administration announced its comprehensive childhood immunization initiative there has been widespread debate on this issue; lengthy, and thoughtful, sometimes contentious. I think it is good. I think it is essential. I do not think anything this important should have no less open discussion.

Today we will discuss the outcome of this debate as seen in the revisions of the administration's proposal. These revisions, I think, are a step in the right direction and I look forward to taking a look at them and hearing the Secretary's explanation of the thought behind the changes that were made.

But I would like to simply underscore a point that I feel very strongly about. That is that we have to get this right. Doing every-

thing in the hope of getting it right is not good policy. It is not a wise use of public or private dollars. It is not fair to the nation. We want to make sure that every child in America has the opportunity and is immunized.

We want to do this in the most thorough way. We want to break down barriers. We want to provide the economic resources necessary to assure that poor children have access to immunization. And we want to continue the kind of research that will make the breakthroughs that will reduce the incidents of disease in the first place.

I think that is the balance that we seek here. Certainly the balance that I seek and I think the administration has listed carefully. We will have some questions and further develop your positions.

I thank you very much.

Senator RIEGLE. Very good.

Senator Danforth?

OPENING STATEMENT OF HON. JOHN C. DANFORTH, A U.S. SENATOR FROM MISSOURI

Senator DANFORTH. Mr. Chairman, the last time I attended the hearing on this subject Secretary Shalala sat for about an 1½ or 2 hours listening to opening statements and I will not inflict that on her today, except to welcome her and also to welcome my law school classmate and friend, Marian Wright Edelman, today.

Senator RIEGLE. Very good.

Senator Kennedy?

STATEMENT OF HON. TED KENNEDY, A U.S. SENATOR FROM MASSACHUSETTS

Senator KENNEDY. Let me say first of all I thank Senator Riegle and members of the Finance Committee. The Labor Committee wants to work closely with the Finance Committee on this program to see that purchasing at the lowest cost will provide adequate reimbursement to the manufacturing companies.

We must also make sure that we have a public health system that is going to reach out to children, particularly the needy children and particularly the poor children.

So we are working very closely with this committee. We are going to have a markup on the 19th on the outreach aspects of the President's program. I want to commend the President for focusing the Nation on this important, cost effective, meaningful program for children and the neediest children—the 3.5 million American children under two who are not able to get this kind of basic and fundamental protection.

So I commend the President and I commend Dr. Shalala. I think it is a real indication of movement on public policy. We had other approaches that were suggested. But now we have this program and we want to move forward. This is a critical time. We want to get it right, but we also want to get it.

There are too many children out there now who are not getting immunized. We want to be sure we make progress on childhood immunization.

I thank the Chair very much and I would ask that my full statement be a part of the record.

Senator RIEGLE. Without objection. We will also include Senator Pryor's statement.

[The prepared statement of Senator Kennedy appears in the appendix.]

Senator RIEGLE. Let me say, Madam Secretary how pleased we are to have you here today and how much we appreciate your vigorous leadership on this issue and every other issue that you have taken up since coming into this position.

For those of us who share a deep concern in many of these issue areas, the energy and vision that you bring is much appreciated. I want to just thank you today for all the hard work that you and your team are doing and have done on this particular issue.

We will make your full statement a part of the record. But I would like you to go ahead now and give us your comments.

STATEMENT OF HON. DONNA E. SHALALA, PH.D., SECRETARY OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC

Secretary SHALALA. Thank you. Thank you very much, Senator.

Mr. Chairman, let me start by saying that we are particularly pleased to testify before your Subcommittee today on what we think is a vitally important issue—immunizing our children against preventable infectious diseases.

As you know, this is my second visit to the Senate to discuss this issue and I am proud to reaffirm the Clinton administration's commitment to immunizing children, all of our children.

Today I want to discuss the state of childhood immunizations in the United States and describe the actions taken thus far by the administration to improve our Nation's immunization policies and review the key provisions contained in the President's comprehensive child immunization proposal.

The problem is enormous. Although 95 percent of school-aged children are properly immunized, our pre-school vaccination rates or dismal. According to the Centers for Disease Control and Prevention some 40 to 60 percent of American toddlers have not received the proper vaccination series by their second birthday.

In some inner city areas the vaccination rate is as low as 10 percent. A brief look at this first chart shows that to be fully immunized a child must be protected against nine diseases. Administering the entire sequence of shots is no easy matter.

Full immunization requires that a child be inoculated 18 times with 5 vaccines and all but 3 of the 18 doses should be received by age 2. This regime would require five additional visits to the doctor's office in the first 2 years of life—at 2 months, at 4 months, at 6 months, at 12 months and at 15 months.

America's immunization delivery system is in shambles. Reductions in resources, increases in disease incidents and patient shifting from private providers to public sector clinics have outstretched our abilities to identify children who need vaccinations and provide them.

There are not enough clinics, and where they do exist, they are often understaffed and closed during critical hours. American families are getting squeezed by the skyrocketing prices of vaccines.

As this accompanying graph illustrates, the vaccine cost to fully immunize a child has increased significantly from 1982 to 1992. In

1982 the cost of vaccine to fully immunize a child in the public and private sectors was approximately $7 and $23, respectively. By 1992, these costs had risen to $122 in the public sector and $244 in the private sector.

In part, these increases can be attributed to recommendations for new vaccines, additional doses of existing vaccines and an excise tax used to fund the vaccine compensation program. But these factors do not account for the net increase in the cost of existing vaccines.

For example, another graph I would like to share with you shows that in 1982 the measles, mumps and rubella—or MMR—vaccine cost over $10 per dose in the private sector, but by 1992 the same dose cost over $25. Even if you subtract the $4.44 per dose excise tax instituted in 1988, the price of the MMR vaccine still doubled.

The diphtheria, tetanus, and pertussis vaccine, or DTP, increased even more sharply, from 37 cents in 1982 to a whopping $10.04 in 1992. With the $4.56 excise tax excluded, that is a net price increase of $5.11, or almost a 14-fold hike per dose.

What is the societal cost? According to the most recent estimates from the CDC, the failure to immunize our children on time led to the measles resurgence between 1989 and 1991. This epidemic resulted in over 55,000 cases of measles, 130 deaths and 11,000 hospitalizations and 44,000 hospital days, with an estimated $150 million cost in direct medical costs.

That does not include the massive indirect cost stemming from lost time on the job, lost productivity, and lost wages for families, costs and heartache that could have been avoided by merely providing families with a vaccine that cost about $24 a dose in 1988.

I would like you to look at another chart that I brought here today. It graphically illustrates that the United States has one of the lowest immunization rates for pre-school children when compared with European countries. And note that for the United States the percentages are for children from age 1 to 4, while the European figures are for children under three for DTP and polio and under two for measles.

Parenthetically, I would also note that data from the World Health Organization places our immunization rates for one dose of measles vaccine by 24 months of age behind countries such as Argentina, Costa Rico, Grenada, and even Cuba.

We cannot allow this situation to continue. We must ensure that our children are appropriately immunized against preventable infectious diseases. To accomplish this we have proposed a coordinated action plan designed to remove the existing barriers to childhood immunization.

As you know, the President's jobs bill included an additional $300 million to strengthen this country's immunization infrastructure. These funds would have helped communities to immediately strengthen delivery systems, to broaden outreach efforts, to increase access to immunization services, to enhance parent and provider education programs, and to provide a host of other essential activities.

We continue to believe that these resources are desperately needed at the local level to improve vaccine delivery systems and immunization services. In response to that need, the President's fiscal

year 1994 budget request for the immunization program at the CDC almost doubles, from $341 million in fiscal year 1993 to over $667 million in fiscal year 1994.

With this renewed commitment, the CDC will be able to fund the State immunization action plans for infrastructure development. The fiscal year 1994 request would also provide the States with the seed money to begin to develop State-based vaccine and immunization registries.

I am pleased to announce today that I have asked the Director of the CDC to create a National Immunization Program that will report directly to the CDC Director. The establishment of this high-level organization within the CDC to oversee our National efforts for childhood immunization is in keeping with the President's and my Department's initiative to ensure that all children in the United States are protected against vaccine preventable infectious disease by their second birthday.

This organizational change will increase the visibility, focus on the importance, and prepare for future improvements of the childhood immunization program. However, these endeavors alone are not enough. We, the elected and appointed leaders of this Nation, must commit ourselves to ensure that all children are appropriately immunized by 2 years of age.

We know that the high price of vaccines is a significant financial barrier to obtaining vaccinations. We also know that the absence of immunization registries has impeded local and State efforts to ensure that all children are vaccinated on time. We must maintain a viable vaccine injury compensation program to increase public confidence in the safety of vaccination.

And finally, information for parents on the benefits and risks of vaccines must be presented in clear, concise and understandable terms.

Mr. Chairman, as an original co-sponsor of the President's Comprehensive Child Immunization Proposal, you well know the problems we are facing. We believe that proper immunization should be a basic right for every child in America, rich or poor, just like in most other industrialized countries.

As originally advanced, the proposal authorizes the purchase of all vaccines by the Federal Government to be given at no cost to providers. Such a program would end the overburdening of our public health facilities by stopping patient shifting from private providers to public clinics and reinforce the essential link between the child and the family physician or the pediatrician, and help build the nation's vaccine manufacturing capacity by stimulating competition in a stable and assured market.

But most importantly, we believe that providing vaccines universally to all children is the best means to achieve the desired end—the immunization of all children at appropriate age.

The best example of how universal distribution makes a difference is the State of Washington. Washington began its universal system in September 1990. The number of doses administered in Washington has climbed from 608,000 in 1990 to 835,000 in 1992. Almost all of the additional doses were administered by private physicians.

As a result, the percentage of immunizations administered by private physicians has climbed from 57 percent in 1990 to 69.1 percent in 1992. This 40-percent increase in the number of vaccinations administered by private physicians proves that private providers will participate in a universal distribution program.

As we all know, despite the inherent advantages of universal purchase, considerable resistance to the Federal purchase of vaccines for all children continues. We believe that the immunization crisis requires that we move forward this year and establish a program for immunizing the greatest number of children.

As a result, we have in collaboration with the House Energy and Commerce Committee refocused the universal access provision and reduced the cost of this portion of the initiative.

As you know, we are also discussing these modifications with the Senate Finance and Labor and Human Resources Committees. Under the new provision, vaccines would be provided to States for free distribution to health care providers who serve children enrolled in Medicaid or who do not have health insurance that covers immunization services.

Such providers would not be allowed to charge patients for the cost of vaccines, but could require a fee for vaccine administration. States could also choose to purchase vaccines at the CDC negotiated price for other segments of their population. By freeing up these resources, the States could reinvest these funds in outreach and educational programs.

In addition, the provision would increase immunization levels of children receiving Medicaid by requiring States to reimburse providers reasonably for vaccine administration. Medicaid programs would require States to set immunization administration fees high enough, that is, competitive enough, to guarantee access to providers on a par with the general population.

States will be able to finance the increased reimbursement with the savings they will realize from our new vaccine purchase arrangement. We cannot ensure that children are immunized unless their families and health care providers know which vaccinations they need and when they need them.

That is why the President's proposal provides for State-based immunization registries. The system would notify parents when immunizations are due and remind them if they do not keep appointments.

Providers would be required to report to the State registries data for each vaccine administered. The efficiency and safety of vaccines would be monitored by linking vaccine administration records with adverse events and disease patterns.

The administration proposal would require that security measures be established to assure the confidentiality of the information collected. Federal grants would be provided to States to establish and operate State- and local-based registries, containing immunization histories, types and lot numbers of vaccines received, health care provider identification, demographic data and notations of adverse events associated with immunizations.

State information systems would be coordinated at the national level by linking the State systems and transferring immunization records if the child's family relocates to a new State.

A functioning National Vaccine Injury Compensation Program is critical to the national immunization effort. The very few children who suffer vaccine-related injuries must be compensated for those injuries and so should their families.

We will also continue to seek reauthorization to make payments from the Vaccine Injury Compensation Trust Fund and to provide for the reinstatement and permanent extension of the vaccine excise tax so that funding would continue to be reserved for the compensation program.

Finally, because there has been considerable misinformation about this proposal, I want to speak to what it does not do. It does not establish a Federal requirement that all children be immunized against the wishes of their parents or guardians. It does not establish a Federal registry system that will force children to be immunized, nor one that will track children for some undefined motive.

Great nations invest in their people and no investment is more fundamental or more cost effective than immunizations. We can and must develop a comprehensive program to reduce barriers to immunizations and to protect our children. We believe that the future of our country and our greatest natural resource, our children, is at stake.

Thank you. I would be happy to answer any questions you might have.

[The prepared statement of Secretary Shalala appears in the appendix.]

Senator RIEGLE. Thank you very much.

Let me just say that I support the improvements you have made to the Federal purchase portion of this comprehensive plan. I think by focusing on young children of greatest need and preserving a private market for vaccine purchases, I think you have addressed the concerns that some have voiced.

I am wondering if you can discuss with us the net costs of this new version. I mean by that the costs of the purchase program and the fact that it is offset in part by savings in Medicaid. What do you see the net cost as being and how many children do you see us covering?

The preliminary estimates which are not the CBO estimates yet, and I think the CBO estimates will be coming in, are that the cost to purchase the vaccine, which will be about $300 million, I would only caution that these are early estimates and we will have the final figures as soon as they are available.

Senator RIEGLE. Now, let us say that number turns out to be right. Is that a gross cost or is that in effect a net cost?

Secretary SHALALA. It is a net cost; and the number of children to be covered is 15 million.

Senator RIEGLE. Fifteen million children. Very good.

Secretary SHALALA. That is our estimate of the group of Medicaid kids plus the kids that are not now covered.

Senator RIEGLE. Right.

Senator Durenberger?

Senator DURENBERGER. Madam Secretary, first, I want to compliment you for your commitment to the issue and your commitment to everything. You have been fantastic.

Have you had an opportunity to look at our bill—the S. 886 and S. 887?

Secretary SHALALA. I have not. I have been briefed generally on it, Senator, and I understand that we are very close in terms of our ideas about how the program might work.

Senator DURENBERGER. I do not want to ask a lot of questions because I have we are moving in the general direction and I hope that we can work out whatever might be appropriate, the differences.

Obviously, one of the concerns that each of us, and in different ways have expressed, both at that Energy and Commerce and Labor and Human Resources hearing and of particular concern to me—I sit on both of these committees. So I really am hopeful that this can bring us together.

It is the investment in vaccines and/or the investment in access to immunization. One of the things we are hoping for in our approach is that while our dollars are different, we also thought in our approach we might be raising the percentage of people that if you look at this on a State-by-State basis that actually are going to end up being immunized.

We looked at the experience of 11 States in this country that provide free vaccines to all children and we find out that the average 2-year immunization rate in those States if 65 percent. So we come to the conclusion that there is more to this problem than the price of the vaccine.

I think we all know that part of it is the cost of the delivery of the service and part of it is difficulty if you are going to get moms to get their very young kids in five different times over a relatively short period of time.

We heard today riding back from the White House about the difficulty that—I think it was Nancy Kassebaum talked about the difficulty that her daughter related to her for Federal employees, to get time off to have their kids vaccinated. They have to take some part of their annual leave in order to get off and do this five times.

So it strikes me that we have a variety of other problems with which we are presented. And if I must describe our approach in some way, it is an effort to begin a process of community-based, State-based efforts to increase that percentage while we hold down the cost by doing this vaccine immunization program, with a lot more flexibility in it than might be suggested by a national vaccine program.

Now let me just ask if you have an observation about how much more—if we wanted to get as close to 100 percent as we possible could go, what will we have to do besides what the administration has already presented to us by way of the modified immunization program? What else would advocate that for the nation?

Secretary SHALALA. Well, Senator, I think that we are very close together in our understanding that we have to begin by rebuilding the delivery system, the infrastructure. What we are talking about is the need for universal access.

One of the reasons that the first step of the immunization effort was put in the jobs bill is because we wanted to start immediately to fund the State action plans developed by communities and States. We wanted to fund those strategies. And, unfortunately,

with the loss of that bill, we will not be able to start as quickly as we wanted to.

So that piece is in this bill. We have always conceded, because everyone has told us the same thing, that we had to rebuild the access system, the delivery system, provide longer clinic hours so that working parents can take their children to get shots, either from their private provider or from a public clinic, support information systems so that parents understand that they are supposed to get their children in before they are two to get this series of shots, and making it very clear that we see this as part of parental responsibility.

I was at a Headstart center here in Washington today. One of the things they do is transmit information to parents about immunization. They see it as part of their role. The Headstart children that they deal with are a little older than 2. But often those families have younger children, too.

So it is putting all of the pieces together. We have never said that price is the centerpiece, but only that it is one critical piece. Because what the pediatricians and the studies have said to us is that you have to have all these pieces in place, but begin with the infrastructure development.

One of the reasons that we argued for universal purchase, I would suggest, is because the States that have had universal purchase plans have had higher immunization rates than the non-universal purchase States. What that suggests to us is that price and access to vaccines is a part of the overall strategy.

And, finally, let me reassure you that we are not interested in building a new, huge Federal bureaucracy. We have always believed that this was going to be a bottoms-up process that beginning by funding the State action plans which were developed by the States, working with their communities, was the first and most critical part; and that this effort was, in fact, going to be carried by communities and by community-wide efforts as well as national efforts.

We see ourselves as providing guidance in leadership, not as line managers of a national immunization program.

Senator DURENBERGER. I see my time is up. An observation I was reminded of when you talked about your visit to the Headstart operation here in Washington, one of the things in our bill is—I do not know what they call it, but I call it like the Motorola of immunization.

In other words, all Federal agencies that have an opportunity to deal with people who may be uninsured, people in one way or another are part of our social insurance system or welfare, something like that, will participate in the effort, facilitate access to immunization and a variety of other approaches.

I see my time is up. Thank you.

Secretary SHALALA. Thank you.

Senator RIEGLE. Senator Rockefeller? I am just going to go back and forth.

Senator Rockefeller, did you have a comment you want to make at this point?

Senator ROCKEFELLER. No. A question?

Senator RIEGLE. All right.

Senator ROCKEFELLER. Is that legal?

Senator RIEGLE. Go ahead.

Senator ROCKEFELLER. How do you track kids on this as parents move from State-to-State in a very mobile society and also tracking as to fit both the public and the private process? How does that work?

Secretary SHALALA. Well, what we intend to do is to develop State-based tracking systems that fit together essentially. So that the records of a child can be transferred from one State to the other. That is a national role that we can play. That is, designing a tracking system so that everybody is basically using the same kind of system. So that if a child moves in the middle of his or her series of shots to another State, those records can be transferred.

Senator ROCKEFELLER. Do you know the Children's Health Fund in New York City?

Secretary SHALALA. Yes.

Senator ROCKEFELLER. They have done some remarkable work on pediatrics, preventative, all kinds of things. They have got a mobile van in West Virginia, in three of our southern counties. It is a fascinating thing because it is tied in with the Marshall University Medical School, computerized records are all there. They stop at the same place at the same time each week, usually with the same physician, the same nurse, nurse practitioner, whatever.

And we found that in the first year and a half that kids nor parents show up. Now I understand that, having been a vista in West Virginia, that it takes a long time for people to feel comfortable, even with health care that comes right to them, which is not usually the case.

So my question is, given that mentality in both inner city and rural areas, the whole question of the public education campaign and how is it that we get rather quickly parents to understand and to bring and, therefore, to be able to vaccinate?

Secretary SHALALA. I think that what we have learned about outreach is that you have to approach it from every direction you possibly can; and everyone in the community has to encourage young parents. And it has to be an expectation of their responsibility as parents.

We have to communicate with them early on when the children are born what our expectations are and what they need to do to bring up healthy children. But then the message has to come to them in a variety of different ways. And those States that have been successful in increasing their immunization rates, if you ask them what they did in terms of public communication, they said everything they could think of, using every leader, every medium, every kind of focus they could bring to bear and repeated it often enough so that the public education really had an impact.

The other thing—and Senator, you are really one of the great leaders in this country on this—we need a health care system to which parents and every American feel connected. And for the large number of Americans that do not have their own physician, that use emergency rooms of hospitals, they do not see that clinic as having an ongoing relationship with them.

One of the things that we are very anxious to do is to make sure the clinics for those who are going to use the public system, and

the pediatricians for those that we use their private system, begin those relationships so there is a continuity of care that goes way beyond immunization.

I have argued that we see immunization as part of an overall prevention strategy. It is more than just immunization that we are urging on parents and on these young families, it is the connection to the health care system.

Senator ROCKEFELLER. Which also means, therefore, the connection to Title V and to the WIC program.

Secretary SHALALA. Exactly.

Senator ROCKEFELLER. And how you interface. I hate that word. But however you connect parents and families to those public programs and the process for that.

Secretary SHALALA. Exactly.

We have tried. We did a demonstration with the WIC program, working with the Department of Agriculture, to see whether we could make a connection between incentives for immunization. And, in fact, the WIC demonstrations did, in fact, significantly increase immunization rates.

What that suggests is that all the connections we can make with programs that are positive incentives, that are supportive of families, will help us to improve immunization rates.

Senator ROCKEFELLER. Thank you, Mr. Chairman.

Senator RIEGLE. Thank you.

Senator Danforth?

Senator DANFORTH. Madam Secretary, this is such an important area. We are going to pass legislation and it is going to be very positive. I want to join everyone else in expressing our appreciation and congratulations to you. You have modified the legislation and it is a step in the right direction and I appreciate what you have done.

It is easy to focus on where we differ and I am about to do it because that is what makes for the discussion. But I also do want to emphasize the areas where we agree. This is a very important issue. It is an issue that should not exist.

It really is ridiculous in this country where for polio vaccinations for kids who are 1-year-olds we rank behind countries like Pakistan and Albania. We should fix it and we are going to fix it. I do applaud you and the President for your leadership in it.

The big lightening rod issue originally, which I thought was an unnecessary issue, was universal purchase. The administration has now modified its position somewhat. I would like to see a little more modification.

It is my understanding that in the modified version of the administration's program, if a person, regardless of means, does not have coverage for vaccinations in that person's insurance policy then vaccinations would be provided free.

I think that the effect of this new program would be that insurance coverage would simply not cover vaccinations.

Secretary SHALALA. The bill that we are recommending actually will have a provision in which we will try to prevent insurance companies from dropping immunizations. I should say that first.

But let me point out, Senator, that under the current system parents whose insurance premiums do not cover immunization can use the public system.

Senator DANFORTH. That is right.

Secretary SHALALA. And we do not have a lot of evidence that insurance companies are running around dropping immunization because they know that the public system is available for free insurance. So I would simply make that point.

We have tried to refocus. And to be fair to us, if there is any telling point about how important we think getting the children in this country immunized is, it is our willingness to listen very carefully to the concerns of many of you about how the program ought to be focused.

Let there be no doubt in your mind that we are deeply committed to getting every child immunized and our willingness to listen ought to reflect that. It is not as important to us—the design of the delivery system—as it is listening to those with evidence that we ought to design it one way or another so it will work.

So it is the level of our commitment that I hope you understand.

Senator DANFORTH. I understand it and I also really do applaud it. What I said is, I am pointing out the differences. But I think we share many common goals?

Secretary SHALALA. Let me also point out to you that if you look at the health plans of upper income and middle income people in our society, working parents—as we have been doing as part of health care reform—the vast majority of them cover immunizations or the parents pay for them themselves. So that we are focusing very much here on those who are not covered for one reason or another.

We know about the referrals from pediatricians and the pediatricians have said to us that they are referring working class parents who do not have coverage to public programs.

Senator DANFORTH. I know. I mean, we really have focused on that in our approach with a vaccine replacement program.

Secretary SHALALA. And you also know that we are very anxious to use private physicians. We are not anxious to build a huge, public bureaucracy, even though we need to rebuild the public health system and delivery system and expand the hours.

We very much want to continue to use private physicians and private pediatricians.

Senator DANFORTH. Right. Well we too have ideas on that and I hope we could continue to have discussions on it.

Also, it is my understanding that in the administration's second version, if States want to adopt universal coverage they can do so and the vaccines would be purchased by COC.

Secretary SHALALA. By the States through CDC.

Senator DANFORTH. All right, by the States through CDC. It would be the same thing though, would it not? I mean, in other words it would be a national purchase system.

Secretary SHALALA. Well, no. It would be a State-based purchase system. The States would be allowed to purchase vaccines at the CDC price.

Senator DANFORTH. But, I mean, the price would be——

Secretary SHALALA. They would be using their own money. We are not talking about a national system in the sense that they would be using Federal money. The States would be using their own money to purchase.

Senator DANFORTH. Okay.

Secretary SHALALA. And that would continue the current system in which States use their own money if they want to run a universal purchase program.

Senator DANFORTH. I know. But unlike the present system, the price would be negotiated nationally, right?

Secretary SHALALA. Some of the States currently can purchase through the CDC at those prices or are able to buy at those prices working with the vaccine companies.

Senator DANFORTH. Well, let me look into it further. It is my understanding that you intend to accomplish something that is different than what the 11 States now do.

Secretary SHALALA. I think the principal is the same. That is, to let the States add on to what the Federal targeted program is so that they can design their own program, their own State-based program.

Senator RIEGLE. Are there any other questions for the Secretary?

[No audible response.]

Senator RIEGLE. If not, let me thank you very much.

Senator ROCKEFELLER. Can I just make one comment? One of the reasons that I am so glad that this is going to happen, that Senator Danforth indicates, too, is that it is a very small step in a very large agenda for children and I keep noting that the national average for poverty in 1990 was 14 percent, for seniors it was 12 percent, for children it was 20 percent.

So that this first step, sometimes when you take the first step the second step is easier. That is one of the reasons I am really happy that this is going to go forward. We have a lot of work to do.

Secretary SHALALA. Thank you, Senator. Thank you.

Senator DANFORTH. Could I first—and I am sorry to detain you—but if I could, Mr. Chairman, make just one additional point.

There is a controversial issue which we have not touched. It is whether the legislation should provide the States with the option, State-option, to require immunization for children as a condition for receiving the adult portion of AFDC payments.

And I would have no objection of doing the other side of that, which would be to condition the personal tax exemption for dependents on the same basis.

I think that would now be possible under State law. But in any event, the purpose of doing it is to use as a model the success of having older kids immunized.

The success rate is good for kids who are 6 years old because it is a requirement—to go to first grade you have to have shots. There is no such requirement for younger kids. That is the reason for that proposal.

I think when you testified before the Labor Committee you did express at least some interest in this kind of concept.

Secretary SHALALA. I particularly expressed interest in positive incentives. My reluctance is always that, if we are adding adminis-

trative burdens, I believe in positive incentives. But when we start linking a whole bunch of programs and a lot of paperwork, I would just as soon avoid that.

There is a difference between a statewide mandate for children to be immunized before they go to school and tying specific Federal programs to immunization. And the only thing I said, Senator, as I said in general about the bill, is that we are so focused on getting this done and making sure that the children in our country get immunized that we, of course, will review any proposal openly and I hope thoughtfully.

Senator DANFORTH. I appreciate that. I mean, my thought would be that if AFDC provides funds for parents to take care of kids, it is not unreasonable to expect the parents to take care of kids in something as important as immunization.

Secretary SHALALA. I think we ought to have high expectations for every parent in this country, whether they are on AFDC or any other program.

Senator DANFORTH. Sure. And I would say the same thing for the tax—as I said, for the tax exemption.

Thank you very much.

Secretary SHALALA. You are welcome.

Senator RIEGLE. Thank you again, Madam Secretary.

Let me call the next set of witnesses to the table. Dr. Cooper, Dr. Edelman, and Ms. Snarr, and Dr. Samuel Katz. If you want to come on up and get situated.

Let me just say a word of introduction to our next panel of witnesses and welcome all of them here. Marian Wright Edelman, of course, is the president of the Children's Defense Fund and she is here, of course, to discuss the importance of the national immunization effort for children across the country.

I am very pleased to introduce Heidi Snarr from Michigan, who is a young mother who is coping with the issue of getting her child vaccinated. She is here today to talk about how the high cost of vaccines has been a problem for her in getting her children immunized at private doctor's offices. That is a problem we are very familiar with.

You have brought along your own daughter, Beth Anne, who is in the front row there and has been so patient today. It is important that she be here though as a representation as to who it is we are trying to help with this legislation.

And then Dr. Samuel Katz, who is a professor of pediatrics at Duke University, School of Medicine, who is also chairman on the Advisory Committee on Immunization Practices. He is a national expert on vaccine research and he will discuss what needs to be done to get our children immunized.

Then, finally, Dr. Lou Cooper is a director and professor of Pediatrics at St. Luke's Roosevelt Hospital Center in New York and is representing the Academy of Pediatrics. He is going to talk to us a bit about the problems that private doctors face.

So we will go in that order. Ms. Edelman, we are pleased to have you back today. We will make your full presentation a part of the record and we would like to hear from you now.

STATEMENT OF MARIAN WRIGHT EDELMAN, PRESIDENT, CHILDREN'S DEFENSE FUND, WASHINGTON, DC

Ms. EDELMAN. Thank you, Mr. Chairman, and thank you for your leadership. I want to just begin by agreeing with my friend, Senator Danforth, that it is ridiculous that we are here discussing this issue today and how ashamed I have felt over the last several weeks as I have listened to representatives from the poorest countries in the world—Africa, Latin America, Asia—share their success in raising childhood immunization rates over the last decade.

According to UNICEF's most recent report, between 1981 and 1991, immunization rates for infants against measles in developing countries rose from 18 to 77 percent. Yet I am ashamed to admit that our rates were hovering around 55 to 60 percent, which our friends abroad have been shocked to hear.

I hope that we can move with a sense of urgency to get our children immunized and to keep them from being at risk from preventable diseases.

Secondly, I want to just emphasize what some witnesses today will testify to, that our immunization crisis is not just that of inner city poor children. CDC data show that the immunization crisis is hitting most of American families. Only 59 percent of white children were up-to-date and just 61 percent of children living in suburban areas were fully immunized.

Among children with family incomes above the poverty line, nearly 40 percent did not have their shots on time. Non-poor children accounted for two-thirds of all children who were behind on their shots.

I believe that like fire departments, fluoridated water and street lights, preventing communicable diseases is an essential public service that is needed by the entire community.

We supported very strongly the President's initial proposal because it was comprehensive, because it will increase demand from parents through more education and outreach, and parents have to be responsible and we have to beat every bush to make sure that they know when to come in and how to come in, and we also have to make sure that the services are in place, in a convenient way, that the transportation is there, that the language is friendly and we need to rebuild our public health system which has decayed over the last 12 years of neglect. We need the vaccination registry, as the President proposes, in every State to monitor our children's immunization status, and we also need to help financially pressed, lower and middle income parents by creating a universal vaccine assurance system. I am appreciative that we have had this compromise. But I do hope we will hold the line where we are so that we can get on with assuring as many American children's access to immunizations as we can.

We believe strongly in the universal distribution system. We agree there should be a system of purchase for Medicaid children and for those children who are uninsured or underinsured for immunizations. I hope that you can figure out a way to prevent insurance companies from not covering the people they now cover. I think that you can do that.

You heard the Secretary's response that cost of vaccines has been one of the significant causes. We have never contended that it is

the cause or the solution, but cost has been one significant problem; and I think it is unconscionable that the cost of vaccines alone to fully immunize a child through the pre-school years has climbed from less than $11 in 1977 to over $230 in 1993.

The drug companies say the increase is due to excise taxes and new vaccines, not excess inflation or big profits. But that is only partly true. The cost to fully immunize a child, not including excise taxes and new vaccines, rose an average of 44 percent a year between 1977 and 1993. The cost of DTP vaccine, not including excise taxes, rose an average of 174 percent a year from 1977 to 1993.

The point is that regardless of the reason for the big vaccine price increases, middle class as well as poor parents now too often lack access to affordable immunizations for their pre-school children and we have to make access affordable while taking the other steps that are also necessary.

The increased costs, coupled with declining incomes of young families, have made immunizations a more burdensome expense. Low and middle income parents are increasingly unable to afford immunizations for their children from their own family doctors and pediatricians. We cite a Dallas study that said that over 70 percent of pediatricians and family doctors referred some of their patients to public clinics. They indicated that the number of children the doctors referred to public clinics increased nearly 700 percent during the previous decade.

We have cited a California study in which 61 percent of public immunization clinic patients had a family doctor or other medical home and would have preferred to have their children immunized at those sources. In a Texas Department of Health survey, that the average income of families going to public clinics was over $25,000 in 1989. The pediatricians who are here can attest to these trends more effectively than I need do at the moment.

I want to just address two myths that I think have been circulating about this bill. The Secretary addressed some of them. The first is that a universal vaccine system will hurt vaccine research and development. And, obviously, none of us are in favor of that.

The President's proposals require that the government pay a fair price that reflects not just production costs but additional research and development expenses and profits sufficient to encourage future additional research on new vaccines. We are all very interested in assuring that that occurs.

Secondly, people have noted that our children get immunized when they enroll in school and wonder why we have the problem with pre-school children. Far more visits for immunizations at a far greater cost are required before 2.

And, third, there has been some contention that those States that have universal vaccination programs have only slightly better immunization rates. I assume that some of our other witnesses will talk to that. But many of the universal States have not really provided all of the vaccines. And, again, one needs to put all of the pieces in place to assure that all children are immunized.

It is our understanding that States like Vermont, which have universal purchase but also have registries and other things do the best. There is some evidence, significant evidence, that these things do make a difference.

I just hope that we can move quickly to do it right as Senator Bradley proposed. We do think that the approach that the President has taken, and that the Chairman's leadership has provided on these bills, will do that. And we and many other groups are supporting that because I do hope that we will not wait another long period of time that keeps our children at risk before taking the kind of action that will be needed. We look forward to working with you.

Senator RIEGLE. Thank you very much. I appreciate that. And I appreciate again, as I have said before, the great leadership that you give on this issue and other issues related to children and their health.

[The prepared statement of Ms. Edelman appears in the appendix.]

Senator RIEGLE. I want to go next to our young mother who is here, Heidi Snarr, who is here with her daughter, Beth Anne. And you have another child as well. You have two children.

I want to thank you for coming from Michigan today to testify and to tell us what it is like for a family like yours where you are going to a private doctor and you are attempting to get your children vaccinated and the costs that you are facing in doing that, and how it is affecting families like yours. And what would be the impact, if we could get the cost of those vaccinations down, through them being given by private physicians?

Why don't you tell us what you have been dealing with and lay it out for us, if you would?

STATEMENT OF HEIDI SNARR, LANSING, MI

Mrs. SNARR. Mr. Chairman and members of the subcommittee, thank you for the opportunity to appear before you today to speak on the issue of childhood immunizations. My name is Heidi Snarr. I am here to tell you about my struggles and frustrations in getting immunizations for my two children.

I have a son, Matthew, who is 3½ years old; and a daughter, Beth Anne, who is now 16 months. My family, like many families with private health insurance, is not covered for immunizations and has been referred by a private physician to public clinics for our children's immunizations.

We hear talk about the immunization crisis, but the cost of vaccines has become an obstacle in getting our children properly immunized. I truly believe that preventative medicine is best administered by the child's primary care physician.

Timely immunizations are an integral part of ensuring a health period of growth and development for a child. It does not make sense that those of us who are already connected with a health care provider must go to alternate source for immunizations simply because their income or insurance does not allow us to receive the vaccines during our regularly scheduled checkups.

There are many reasons why parents who leave their doctor's office without having vaccinated their children will not get to the Public Health Department. But if costs had not delayed their getting the service, each of these children would be fully immunized.

My family, which also includes my husband, Alan, has been living in Lansing, Michigan for the last 5 years. Alan is a full-time

doctoral student and teaching assistant at Michigan State University. This enables us to purchase health insurance for the family through a student health plan.

My part-time teaching job at a local community college does not entitle me to health coverage. We pay approximately $300 monthly for our insurance plan. Unfortunately, our insurance does not cover immunizations or other well childcare services. It would be a struggle for us to pay the costs of immunizing our children given that our out-of-pocket expenses for health care last year totaled almost $4,500. This amount included payments for premiums, well-child appointments, co-payments and deductibles.

Due to a high-risk pregnancy, my son, Matthew, was born prematurely in the State of Utah. Upon Matthew's birth and stabilization we joined my husband who had already begun his studies at Michigan State University.

My son's first health care provider in Michigan was a resident of the MSU Clinical Center, specializing in neonatology. Because our doctor at the time was aware of our graduate student budget, he informed us about free immunizations administered at the clinical center the third Saturday of each month. As no appointments are taken, we have had to wait anywhere from 30 minutes to an hour for shots.

When we were expecting our second child and were concerned with the possibility of another high-risk pregnancy, our doctor at the MSU Clinical Center referred us to Dr. Hugh Colton, a partner in Lansing Pediatric Associates.

We are pleased with the care that our children receive from Dr. Colton, and we are confident that their early growth and development is being closely monitored by a regular health care provider.

We are aware of the costs of administering vaccines in a private practice. The doctor must cover the cost of vaccines purchased at market prices, as well as his or her overhead. The total costs of a full series of immunizations per child in the first 18 months of life can run upward of $250.

For us, this amount is in addition to the cost of each well-child appointment and our other health care costs for health insurance premiums, co-payments and deductibles.

Because we simply cannot afford this extra financial outlay, we continue to use the free immunization services of the MSU Clinical Center after consulting with Dr. Colton. In the event that we cannot make it to the clinical center or a specified Saturday, we take our children to the County Health Department.

There we have waited with our healthy children for 45 minutes to an hour in a room filled with sick people, exposing our children to unnecessary health risks.

Dr. Colton keeps track of Matthew and Beth Anne's growth and development and reminds us during their checkups to see that they are immunized and that this information is recorded in their office medical histories. I am given no other reminder of when my children are due for the next series of shots.

Fortunately, I have been able to keep my children's immunizations current though it has been difficult to arrange our busy schedule to fall within the operating hours of the clinical center or Health Department.

While I have been able to keep my children's shots current, I have several friends who have not. All of them are well-educated people with private insurance. Like us, they, too, were referred by their physician to the local health department for free immunizations.

Problems due to their work schedules, illness or transportation have made visits to these free clinics difficult. As a result, their children's shots are not up to date. This creates a break in preventative health care.

If costs had not been the factor that initially precluded their having received these shots during a regularly scheduled appointment with their primary care provider, their children would be most likely up to date on their immunizations and not at risk for disease.

Like all parents, Alan I want to do the best to keep our children healthy. This includes providing them with proper preventative health care, the central component of which is the administration of regularly scheduled immunizations.

I am here to tell you today that the current system could be improved by making immunizations more affordable to those parents who choose to take their children to a private physician. If immunizations can be provided by a child's primary care provider at a nominal cost for administering the vaccine, the net result will be that more children are fully immunized against infectious disease.

A greater public good will be served when parents, the health industry, and government can work together in the important task of assuring preventative care for America's children.

Finally, I want to say I appreciate the support of the March of Dimes Birth Defects Foundation in helping me come to Washington, DC, to testify before you. Thank you again for the opportunity to appear before you today.

Senator RIEGLE. Thank you very much. I appreciate that important personal statement and your sharing with us what you have been facing.

[The prepared statement of Mrs. Snarr appears in the appendix.]

Senator RIEGLE. You know, we had a hearing not long ago on this subject when we first introduced the legislation and we had in some of the vaccine manufacturers and we will hear from some after this panel. And one of the interesting, and I find troubling, anomalies in our system is that vaccines today that are so expensive that you found it impossible to pay for them through your private doctor's office, you had no insurance to cover it, those very same vaccines are available today in Canada at a lower price.

And so you sort of wonder how can this be. I mean, how can a country that is immediately adjacent to ours be in a situation where even if they were to face that same problem, the cost of the vaccine in a private doctor's office would be far less because they have managed to buy the vaccines on an overall basis and, therefore, negotiate a better price.

So, in effect, people in America in situations like yours are faced with a situation where either you cannot afford it because—well, you are working part-time and your husband is a graduate student—the cost is so high, so you are driven out of the private doctor's office and you have to go through the public clinic system.

But as you point out, many people do not close the loop. They do not get around to do this. But it is really quite unnecessary that that happened. Because first of all, we are paying, in my view, too much for these vaccines.

Part of the problem that I have with some of the ideological arguments that goes back and forth here is the whole question of how expensive these vaccines are. And should they, in fact, cost more here than they cost next door in Canada; and if so, why?

Why should a young parent like yourself, or a young couple like yourselves, find themselves in a different situation, find it easier to protect their children in an adjacent country on the very same issue that can be accomplished here in the United States because we, you know, have been, not thoughtful enough as a society to engineer our system in such a way that the cost is down at a lower level. So you do not have that same threshold problem.

I am struck, too—and I will just take one more minute and I want to go on to our other witnesses—my wife and I have a fifteen-month-old as well. Allison was just in for her 15-month shots at a private doctor's office on the 30th of this last month, so 6 days ago.

And in going down the billing that is attached to this, it is not just the $52 for the MMR shot and the $36 for the HIB shot, but there is what you made reference to in passing, and that is the well-baby checkup. Because that sort of gets wrapped around this trip in to do this. So these two things sort of relate to one another. That, in this instance, was a $75 charge.

So this one stop for these two vaccinations came to $163. And, of course, that's one of the series of shots. But it is so clear that families who do not have insurance, your insurance does not cover these shots for you. I mean, we have insurance but it is not there to really provide the kind of preventative protection that presumably insurance ought to be providing.

So that is a defect that hopefully we will cure in the comprehensive health care plan. But it seems to me that you illustrate exactly what the problem is. I mean, you are sort of an upward bound young family in America. You husband is earning, I gather, a doctoral degree. You are working part time. You have two children. You are very conscientious about their health.

You had a difficult health problem with your son that is a little older. And here you are in a situation where literally you cannot afford to pay for the vaccines in a private doctor's office because they are higher than they ought to be. They are just higher than they ought to be. So you are being told, look, you take your children and go over to the clinic here and the clinic may be filled with children who are sick, who are there for other purposes, and wait for however long it takes, and you get your shot there.

If we are going to provide the vaccine there, I mean, why is it not just as logical to provide the vaccine in the private doctor's office? Now you can see why the vaccine maker, if they are selling it for a lower price to the public clinic and a higher price to the private doctor, that they would prefer to keep you or anybody else that they can get to get the shots at a higher price at the private doctor's office.

And if the private doctor in a sense is adding on his costs, too, then he has a certain incentive, too, if you are a customer who can

afford to pay the bill, the higher bill, either through your insurance plan or out of your own pocket, then there is a financial incentive for that doctor, other things equal as well, to be able to use this as a source of income and profit for his or her operation.

But when you think about what it is we are trying to accomplish, and that is getting the kids of this country vaccinated. I think it is sort of like the traffic lights on the corner. I mean, we have these things for reasons of public safety. We want to protect the children and we want to protect all children.

And if children aren't vaccinated, I mean, then the problem of these diseases moving around and affecting others just keeps growing. So we are going to continue to work this thing on through. But I appreciate your taking the time to come today. I know it was an inconvenience to come and to bring your daughter here.

But I think it is important that somebody who is going through exactly the problem in this system that is unnecessarily complex, difficult, inefficient, too expensive, has a chance to come and tell that story so we can see if we have enough collective wisdom and will around here to do something about fixing it.

Let me proceed now to Dr. Samuel Katz, who I said earlier is a professor of pediatrics at the Duke University School of medicine and chairman of the Advisory Committee on Immunization Practices. Dr. Katz, we would like to hear from you now, please.

STATEMENT OF SAMUEL L. KATZ, M.D., PROFESSOR, DIVISION OF PEDIATRIC HEALTH POLICY AND INFECTIOUS DISEASES, DUKE UNIVERSITY MEDICAL CENTER, DURHAM, NC, AND CHAIRMAN, ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES, CENTERS FOR DISEASE CONTROL AND PREVENTION, ATLANTA, GA

Dr. KATZ. Thank you very much, Chairman Riegle and Senator Danforth. You are an imposing group before whom to appear. I have submitted a lengthy statement, but what I would like to do is to select a few points that have come out in Secretary Shalala's comments as well as Ms. Edelman's and Mrs. Snarr's.

I have spent 36 years of my professional life as a physician doing research and development in childhood vaccines. And as you have stated, for 8 years I have served as Chairman of the Advisory Committee on Immunization Practices of your Public Health Service.

I think we have to look at history. The prevention of infectious diseases by vaccines is one of the great triumphs of modern medicine. In 1992 in this country the reported cases of vaccine preventable diseases were reduced by greater than 97 to 99 percent from those numbers that occurred in the years of peak incidence.

That is the good side of the ledger. Those records of achievement are eroded, however, on occasions such as have been cited in 1989 to 1991 when we had an outbreak of measles with more than 55,000 cases. And the great majority of those victims of measles were children who suffered its complications, who required hospitalization, and as you heard, 150 died; they were mainly unvaccinated children.

I think they exemplify our failure to provide a simple preventative health measure that should reach every infant and child.

Senator Danforth spoke about polio. I do not know if you are aware that there has been paralytic polio in the Netherlands for 6 months and now in the province of Alberta in Canada the same Type III polio virus that is causing the outbreak in Holland has been isolated among children there.

It is very possible that the virus could cross the border. I think the failure to immunize children appropriately against diseases such as polio leaves us with a serious vulnerability.

Any vaccine distribution program has to include the commitment that the vaccines reach the children. You have heard about access and outreach and I will not reemphasize them, except to say that obviously they are terribly important.

In my State, which is a rural one, North Carolina is the 10th largest State in the country—but there are no really big cities. Rural health clinics, such as Mrs. Snarr has to attend, may only give vaccines from 2:00 until 4:00 on Thursday afternoon.

A single parent or two parents who work cannot get their child there from 2:00 to 4:00. And if they do, after sitting on the bench for an hour, they may get discouraged and go back to their jobs.

The whole public health system, as Dr. Edelman pointed out, has been seriously eroded in the past 12 years and it needs to be bolstered. We are asking them to take care of AIDS, of lead poisoning, of environmental pollution, of a dozen other things. But the same health department that used to have 22 nurses now has 3. I leave that with you as an example.

Another thing that Senator Danforth spoke to was the matter of insurance. I think that every health insurance and every health care program that we allow to be written in this country must include preventative medical measures. It is economically wasteful and it is morally unconscionable that these plans will pay thousands of dollars for care of a child who is admitted to the hospital with measles pneumonia or measles encephalitis, for complex technological procedures, but they will not pay a few dollars for preventative measures, such as vaccines that you heard of from Mrs. Snarr.

We need more culturally appropriate and imaginative educational programs. Our media love to emphasize the bad things that happen in life. They do not emphasize the 99-percent reduction in vaccine-preventable disease and encourage families, who fortunately have not seen polio or measles because they have not occurred in epidemic fashion for so many years. These families do not understand why it is so important to get their children immunized.

Once before, and it seems that this testimony has been given too often, once before when I testified here Congressman Scheuer was among the House of Representatives committee members. He had polio as a youngster so we did not have to tell him what paralytic polio was.

The National Vaccine Injury Compensation Program has to be put back into operation. I know that is part of your plan. Because of frivolous, costly litigation, had only two companies distributing and making vaccines in this country in the mid-1980's and went to a rationing system when one company had trouble with its production.

We are in a good phase now. We have Lederle-Praxis, we have Merck, we have Connaught, we have SmithKline Beecham, we have Wyeth-Ayerst and several dozen recombinant technology firms who are using the modern molecular biology to tailor-make designer vaccines. We can make vaccines for almost everything today if we set our minds and our resources to it.

We have to be certain that these programs are protected. It is absolutely essential that we encourage the continued participation of these new companies and the existing companies in vaccine research and development.

The Federal Government, through the National Institutes of Health and the National Science Foundation, funds the basic research by and large in new vaccine development. However, once we get through a few monkeys, a few guinea pigs, a few mice, and five adults, the big programs for clinical trials, which involve thousands of children, the scale-up to produce vaccines, all of the development, falls on the shoulders of the pharmaceutical firms.

I do not plead on their behalf for the current prices. But I do plead as we look at negotiating prices that we include ample funds for research and development. We do not want to shut that off.

You heard from Secretary Shalala about 15 or 18 shots. I went to meetings, research meetings, this morning where results were presented, showing we are going to reduce those even in this year because of the ability to combine vaccines so that diphtheria, tetanus, pertussis is combined with hepatitis B, is combined with hemophilus influenza B and one shot will replace three.

That development work is going to continue and we must enable those people who are doing it to continue.

Finally, I think that there is no question that if one had to emphasize what are the points on which we all agree, we all agree the costs of vaccines must be reduced in some way so that they are not a barrier to people who do not have insurance or who cannot afford them.

We have to bolster the infrastructure of public health. We have to provide access, ease, massive education, not just to parents but to health professionals as well. We have to restore the National Vaccine Injury Compensation Program. We have to establish a registry and tracking.

I have children who come from Missouri to North Carolina and I ask the mother, "what vaccines has your child had?" "Oh, he has had his shots." "Well, which shots?" "Well, they gave me a record, but I lost it." Well, then I called the Health Department in St. Louis. "Well, we don't have those records." Or they had a private doctor and we call him. Well, "he went out of practice last year and we don't know where his records are."

We need badly a national network with a registry so that when that child drops in, not just for a regularly scheduled visit, but he comes to your clinic with a sprained ankle or a laceration I can punch in my computer and find out that he is also two shots behind and I can make those up while he is there in addition to taking care of his sprained ankle or whatever else.

Finally, I can only say that research and development are the essence of why we are so well off with the available products. We

have not done well in getting them to the children who need them, but we must continue the support of research and development.

Thank you very much.

Senator RIEGLE. Thank you very much, Dr. Katz.

Dr. Cooper, we have introduced you, and we would like to have your statement now.

STATEMENT OF LOUIS Z. COOPER, M.D., DIRECTOR, ST. LUKE'S ROOSEVELT HOSPITAL CENTER, NEW YORK, NY, ON BEHALF OF THE AMERICAN ACADEMY OF PEDIATRICS

Dr. COOPER. Thank you, Mr. Chairman and members of the committee. I am Dr. Louie Cooper, director of pediatrics at St. Luke's Roosevelt Hospital Center and professor of pediatrics at Columbia University.

For me it is a special privilege to speak on behalf of the academy on the subject of immunization and also a special privilege to sit beside my hero in child advocacy, Marian Edelman, and my hero in vaccine development, Dr. Sam Katz, who neglects to mention that he is responsible for the measles vaccine that saved millions of lives throughout the world.

Senator RIEGLE. Hear. Hear.

Dr. COOPER. Your recognition of the slew of vaccines, the complexity of a successful immunization program and the magnitude of our Nation's immunization gap is reflected clearly in the language of S. 733 and its companion S. 732.

In my written testimony, the Academy urged you with enthusiasm to pass these comprehensive bills. Today in the spirit of let us get this job done, we welcome and support the compromise presented by Secretary Shalala because it is an important step forward.

At the joint hearing on April 21, my colleague, Dr. Ed Marcuse, made the analogy that the embarrassing problems in our immunization effort were like a car with four flat tires. There now appears to be remarkable agreement in government and the broader community on how to fix three of those tires and you know what those are—the importance of rebuilding the public health infrastructure, the critical need for a system of registry tracking and outreach, imaginative public and professional educational programs and reactivating and refining the national vaccine injury compensation program.

There has not been agreement concerning the role of cost as a barrier and who should pay that cost. It is appropriate in these hearings for me to focus on that fourth tire, the issue of cost.

Please let there be no confusion about the position of the Academy. We consider cost an important barrier to timely immunization and after listening to Mrs. Snarr I do not think anyone needs to have that reinforced again.

It is clearly not the sole barrier and we echo the need for passage and full funding of the other components of the legislation. But to fail to deal with the issue of out-of-pocket costs to young working parents is to leave the last tire unfixed or vehicle unable to speed forward to prevent another tragic and expensive epidemic, to leave too many children unprotected and our job undone.

A few words about the specific costs of vaccine are in order. Even at current costs, vaccines remain the most dramatic bargain in all of medicine. We are pleased that the proposed legislation recognizes the importance of adequate pricing to ensure continuing compensation for research and development and legitimate profit to ensure continuing strong incentives for industry to stay and to compete in the vaccine business.

History has demonstrated that healthy competition is our most effective tool for assuring a reliable and safe supply of vaccine. We understand industry's reluctance to accept government in an expanded role, but we believe that working with industry you can protect the public's interest by creating a climate which encourages industry to help with the next generation of vaccines, those vaccines that Dr. Katz referred to.

Why are we so convinced that out-of-pocket costs to working families is a barrier to timely immunization? My written testimony offers much more detail, but the heart of the case is the personal experience of our membership, documented in our last immunization survey and certainly reaffirmed by this panel today.

Pediatricians are referring our families to already overburdened clinics because of the cost of vaccine. New York State's Health Department data shows a dramatic upswing delivered in public clinics throughout the State, by the contrast to the experience that Secretary Shalala described in the State of Washington.

The data on the 11 States with universal purchase plans are not easy to interpret because of the different levels of development in each of those States. Many have just gotten into universal purchase and many do not have the infrastructure and we have all heard of the importance of infrastructure.

But the reality is that those States as a group do have better rates than the other 39. And in those States, continuity of care is preserved. The overwhelming number of pediatricians and family physicians who participate in those programs suggests that pediatricians are ready, willing and able to do the job. The experience in other countries is equally compelling.

As to the sticking point of why should scarce government dollars pay for well-to-do middle class children to be vaccinated, several brief reminders are in order.

First, most parents of young children do not qualify as well-to-do. They live on tight budgets. Under the current system, which does delay immunization, these young working families pay out-of-pocket at retail subsidizing lower cost for public purchase.

As a nation, we have made a commitment to the future through support of a free and appropriate education for every child, clean water, safe sewage disposal, and sharing nationally where sole dependents on the States or families would place a disproportionate burden.

We all pay dearly for epidemics and no one here needs to argue the values of prevention. However, success or failure in getting our vaccine program on the road again must include addressing the issue of out-of-pocket cost. The complexity of the task demands that all of the participants in the vaccine endeavor come together to get the details right.

The Academy is eager to work with all of you toward the gift we have the capacity to give—safety from vaccine preventable disease for every child in America.

Again, thank you. We look forward to working with you and the remarks and your questions.

Senator RIEGLE. Thank you.

[The prepared statement of Dr. Cooper appears in the appendix.]

Senator RIEGLE. Let me just go back to you, Dr. Katz. I thought it was a very powerful illustration that you gave about the outbreak of polio in the Netherlands and now we have seen it in Alberta, Canada. So it should be a flashing red light to the risk that we can run all these years after the polio epidemics of decades ago, that some of us here are old enough to have remembered.

I want to make sure I understand your position on universal purchase because you've been referred to by some as someone who might have opposed the program.

Dr. KATZ. Absolutely not.

Senator RIEGLE. Okay. Well, that is what I wanted to clarify. Is it fair to say that you do support universal purchase in the context of some comprehensive proposal?

Dr. KATZ. I certainly do. I have spent the last 2 days here visiting the legislative aides of all the members of this committee and I think I have made my position very clear—that I support universal purchase or some modification thereof that will see that the price of a vaccine is never the obstacle to a child being immunized.

Senator RIEGLE. Very good. I want to thank you all. I am going to yield to Senator Danforth. I think you have all made really exceptional and strong and valuable presentations.

Senator Danforth?

Senator DANFORTH. Thank you, Mr. Chairman. I certainly agree with that conclusion.

Dr. Cooper, my understanding of the present situation in a number of States is that if a parent takes a Medicaid to a private physician and the private physician administers a dose of vaccine and seeks payment from Medicaid, the amount the physician receives as reimbursement is below the cost that the physician has paid for the vaccine. And that, therefore, the physician instead of vaccinating a Medicaid child, being reimbursed at maybe half the cost of the vaccine, and losing money on it, refers the parent and the child to a public clinic.

That is really a hassle factor. The parent goes to one place and then another. And maybe the clinic isn't open. Maybe the parent is working and it is just a considerable run around. Is that true in a lot of States?

Dr. COOPER. Well, as you know, Senator Danforth, Medicaid is a Federal/State program. So reimbursement for vaccine varies a great deal from State to State. There is an incredible hassle factor, including whether you get paid or not. And States are often behind in matching reimbursement to the increased cost of vaccine.

I think what is equally compelling though are our data from our surveys of our membership showing how many non-Medicaid patients we are referring to public clinics. You heard Senator Riegle talk about the incentive, both in terms of better care and the potential financial reward to the pediatrician of immunizing in the office.

And in spite of that, more than half of our members report that they are, because of the cost barrier, referring their patients to public clinics.

So, yes, Medicaid is worse, but it is there for the rest of the community as well.

Senator DANFORTH. Dr. Katz, as you pointed out, Secretary Shalala said that right now there are 18 different shots. Is it shots or is it doses, some by mouth?

Dr. KATZ. I think she's talking about doses and that includes the oral vaccines, yes.

Senator DANFORTH. But in any event, there are 18 different vaccines that a child now has to have.

Dr. KATZ. At different visits, a child could have as many as three different injections at the present time. The DTP, which is a single injection; the hemophilus influenza B conjugate to prevent the most common form of meningitis, which is a second injection; hepatitis B which is a third.

That is what I was addressing when I said that there are now—in fact, there is one new licensed product, licensed as of March 30, that combines two of those. So you can reduce that three to only two shots on several of those visits. And that applies three or four subsequent visits. So you have already reduced 8 of those shots she was talking about to 4.

Senator DANFORTH. Well, I was told yesterday by an officer of a pharmaceutical company that in his view they are going to soon go down to five doses and he believes that around the year 2000 it will be possible to immunize children by just one dose.

Dr. KATZ. Well, you know the holy grail is that we will give a communion wafer to a newborn and that will include all the antigens that we want children to have. That is the goal of the Children's Vaccine Initiative, to which every country, except the United States under President Bush, signed on in 1990 at the United Nations.

Senator DANFORTH. Do not pick on us poor Republicans, Doctor. We are having such a hard time.

Dr. KATZ. No, it was the individual, not the party, I was citing. But basically that is the goal and there is work going on in that direction. You should also appreciate that vaccine research goes on in countries other than the United States—in the United Kingdom and Japan.

Senator DANFORTH. But as I understand it, other than—I think it is—rabies, all of them have been U.S. products?

Dr. KATZ. No, that is not true either. Acellular pertussis vaccine, which was just licensed recently in this country, was developed 10 years ago in Japan. The varicella vaccine, which is about to be licensed, was developed in Japan. Japanese encephalitis vaccine which is now licensed in this country, developed in Japan. Rabies vaccine that you give in this country comes from France.

Senator DANFORTH. We are still doing a pretty good job though.

Dr. KATZ. I think we are doing a wonderful job. Do not misunderstand me. But I think we get a little bit xenophobic sometimes.

May I clarify one thing for Senator Riegle? I do not want you to think there are cases of polio in Canada. The virus that caused the

paralytic cases in the Netherlands is now circulating in Alberta. So if it gets into children who are unimmunized it could cause polio.

But to my knowledge, and I turn to Dr. Orenstein, who is the expert, there have not been any cases yet of Canadian polio, just isolates of virus.

Senator RIEGLE. Well, that is important. But the reason I think you mentioned it is that this is like an early warning.

Dr. KATZ. It is a threat.

Senator RIEGLE. It ought to tell us that it is time to make sure we are fully protected.

Dr. KATZ. The last time that happened it went from Holland, to Canada, then to Missouri, to Pennsylvania and to Iowa, as I remember, among the Amish population who do not have their children immunized.

Senator DANFORTH. Can I just give my punch line?

Senator RIEGLE. Please. Go ahead. Yes.

Senator DANFORTH. I want you to believe, I think this is a very, very serious problem. I will tell you where I first got interested in it. And I guess I am a Johnnie come lately to it as far as everybody at the table is concerned.

But a few years ago I visited St. Louis Children's Hospital and I was talking to the Administrator of St. Louis Children's Hospital and I said, what is the leading cause of admissions right now. I was told that the leading cause of admissions was measles.

I thought that is astounding that the leading cause of admissions at St. Louis Children's Hospital at that point in time is measles. Something has to be done about it.

Well, we really have spent a lot of time trying to figure out exactly what should be done about it. Obviously, cost should not be a barrier. I am not saying, let us get the cost up so high that they are a barrier. What I am saying is that I think there is a very important balancing act and the very important balancing act is to make sure that we have access, that we have outreach, that we have all of the things that we agree on.

That we also proceed with research and development, that we encourage the pharmaceutical companies to do that. My own view is that there is no better encouragement than to allow the market system to work. I do not think that we in Washington are brilliant enough to using a word that Senator Riegle used—engineer how things turn out.

That is why I myself am very reluctant to interfere with the market system anymore than is necessary. Now in our legislation, we provide Medicaid coverage for vaccines for up to 180 percent of poverty.

In other words, we are saying that up to 185 percent of poverty you have free vaccine. And we also say that for anybody who wants to go to a public clinic you get the free vaccine. But what we are saying is, we do not want to destroy the market place unnecessarily. And we do not want to create a situation where somebody who has an income of $25,000 and is a taxpayer is subsidizing the vaccinations of people who are well to do.

So that basically is the theme of the legislation. I think we are very close. I think that we are very, very close to legislation that we can agree on. But I also believe that if we are going to go from

18 doses to 5 doses to 1 dose in the next 10 years that is an objective that is really worth shooting for.

And when you talk about the hassle factor, the difficulty that we now have with all these unvaccinated children in this country, to go to one dose if it is possible to do it would be just a wonderful, wonderful accomplishment. We are not going to do that unless we have people who are willing to take the risk and have the capital to invest in it.

I just would not like to blow up that system unnecessarily. And that really is the whole—that is my punch line. That is the theme of what we are trying to accomplish.

Dr. KATZ. Well, I hope you heard that I agree with you. Research and development must be supported. And in the negotiation of vaccine prices, that is a figure that has to be included.

But let me give you one example, Senator Danforth. From 1982 to 1989 there was only one company in this country that distributed hepatitis B vaccine and it cost over $100 for you or me or your child to get immunized.

In 1989 a second company got into the American market coming from abroad and now you can get vaccine for $21 to $40 to get your child or you immunized. I think that is the sort of competitive market for us that I see as indicative of the fact that there is "wiggle room" some place.

All I am asking is that you negotiate keenly when you negotiate the prices.

Dr. COOPER. Senator Danforth, could I comment for a minute? Because we did get a chance to at least look briefly at your proposal yesterday.

In New York State we do have coverage at that level. But, in fact, it is the families who make $25,000 a year in New York who currently are deprived because of costs of vaccine.

In New York about 60 percent of the children live below or in near poverty and there is a large group just above that. They as a group are the group either without insurance or whose insurance does not cover vaccines. And the fact is that they paying at the retail price are, in fact, subsidizing the lower cost government purchase. I think that is wrong.

I also think that regardless of the price, for those households, certainly in communities with the high cost of living such as we have in our urban communities, that going up to 185 percent of the poverty level is not good enough. It will not do the job. At least that has been our experience in one urban community.

Senator RIEGLE. You know, we have a vote on. I just want to draw that to the attention of Senator Danforth as well. But before we leave for this vote I was listening very carefully and what is missing it seems to me, in what was suggested is, we have not offered an answer in the last approach to Mrs. Snarr who is here or anybody in her situation.

In other words, we are saying in effect sorry we really cannot solve your problem for you. I mean, if she is outside the expanded Medicaid eligibility limit, if she is $1 over that, she probably is, then she is right back where she is right now; is she not?

Mrs. SNARR. Well, the $250 might not seem significant to some people. But on top of the other $4,500 we have already paid for

medical expenses, in our family we equal dollars with diapers. The $250, how many packs of diapers is that. How many jars of baby food is that? How many other things that the children need could we use that money for?

And then in our practical sense, in our case, it is very significant. That $250 is significant.

We have gotten our children the immunizations, but other families have not. And it is the children we need to be concerned about.

Senator DANFORTH. I am sure if we abolished the market system, people would pay less.

Mrs. SNARR. I do not think it needs to be abolished.

Senator DANFORTH. I think that there are adverse consequences in doing that that we should try to avoid.

Mrs. SNARR. Okay.

Senator DANFORTH. And that is why I think we should focus on about 50 percent of the population which would be covered under our program, who would get free vaccines, but to allow a market system to exist for everybody else, and to try to make it possible so that one dose can do the job.

Mrs. SNARR. The adverse consequences are the numbers of children who will go without the vaccine who are at risk and who put others at risk. And those are the adverse consequences of going the other way. In our opinion, that is more important.

Senator RIEGLE. Well, I think it illustrates there is a difference of opinion. I think the question is: How do we solve the whole problem? You know, Senator Danforth makes reference to my word "engineer" and I will use it again. I think we have to try to engineer enough of a sensible change in the system so that we get all the kids protected, on the theory that every child is important and that this is a fundamental base line requirement and need in the country; and that the country is better off for it.

This is an investment that is a public health and a public well-being investment. It is probably the least expensive and the most valuable that we can make.

I mean, we then move on into public education, other things later on down the track, but we have to have well babies and we have to have well children and we have to know how to do that if we are to get the job done.

So I hope in the defense of the market that we do not end up unable to reach most of the people that have to be reached. And, of course, no one is advocating abolishing the private sector, quite the contrary. We are talking about working with the private sector and the public sector. So that is not really the dichotomy.

But we have to have an answer that reaches everybody or otherwise we do not have an answer. We just have words and sophistry and not a response; and we better get a response.

So let me thank this panel. We are going to have to adjourn here briefly while we go over for this vote. Then we have two final witnesses that we will come back for very promptly. So the committee will stand in recess for about 10 minutes.

I particularly want to thank you, Mrs. Snarr, again, for coming all the way from Michigan with your daughter.

The committee stands in recess.

[Whereupon, at 4:27 p.m., the hearing recessed and resumed at 4:42 p.m.]

AFTER RECESS

Senator RIEGLE. The committee will resume. Let me invite those in the room to find seats and let me extend a note of apology to our last witnesses here. It is always inconvenient when the votes come and there is no way to predict when that will happen. So I appreciate your patience and good humor so late in the day.

Let me say that our last panel consists of representatives from three different pharmaceutical companies who produce vaccines for children. Due to time constraints two of these pharmaceutical companies will provide oral testimony today.

Dr. Ronald Saldarini is the president of Lederle-Praxis Biologicals, a division of American Cyanamid Co. His company is American-based and is one of the leading suppliers of childhood vaccines.

I am also pleased to introduce Dr. Garnier, who is the Vice-resident of SmithKline Beecham Pharmaceutical in North America and I appreciate both of you being here with your colleagues today.

Two other companies, Merc and Connaught Laboratories, have submitted written testimony.

[The prepared statements appear in the appendix.]

Senator RIEGLE. And David Williams, who is the president and CEO of Connaught, will be available for questions and we will certainly make those written statements a part of the record.

Gentlemen, we welcome you. Dr. Saldarini, why don't we start with you and then we will go to your colleague.

STATEMENT OF RONALD J. SALDARINI, PH.D., PRESIDENT AND CHIEF EXECUTIVE OFFICER, LEDERLE-PRAXIS BIOLOGICALS, WAYNE, NJ

Mr. SALDARINI. Good after and thank you, Senator Riegle. I have submitted to the committee more extensive comments in writing. In the few minutes I have available, I would like to share with you our principal concerns about the compromise proposal that is now under consideration in the House.

Lederle-Praxis is one of two remaining U.S.-based developers and manufacturers of vaccines and we employ approximately 700 vaccine employees in the State of New York alone. Most of these people are unionized. Lederle-Praxis is, in our opinion, an American success story.

We survived the litigious environment of the 1980's and at the same time we committed substantial resources to incorporate biotechnology's promise into vaccine development. This 12-year investment has yielded three brand new vaccines, all of which have come out over the past 4 years. So, three new vaccines in 4 years.

One of those is a combination product which combines diphtheria, tetanus and pertussis with haemophilus influenza type B vaccine and we definitely expect several more vaccines to follow in the near future.

The problem with the success story is that, in our opinion, it is threatened by the rush to judgment on matters which could have

a very serious impact on our ability and the ability of companies like ours to continue to develop and market new vaccine products.

We have had two problems with the proposed vaccine purchase compromise. I will not discuss the obvious flaws relating to the ability of the government to have unrestricted access to confidential business information, but I will rather focus on two other issues.

One is the definition of uninsured. My company has long regarded the absence of insurance as a good surrogate for identifying those who are truly needy. But a lack of immunization coverage is really a totally different matter. Because about half of the insurance policies in the United States that are written do not cover immunizations.

So there is really no correlation between immunization coverage and wealth or poverty. Thus, from our perspective the uninsured must be defined as someone without health insurance.

The second major problem concerns the unrestricted access which the proposal gives to States to buy all the States' vaccines at a negotiated price. Admittedly, the State must buy this additional vaccine with State funds. But still, it is a concept that we are concerned about.

When we set a negotiated price with government, it is based on an assumption about the volume of sales. All manufacturers function that way. And the proposal would completely undercut any such assumption and would create in effect a universal purchase system over time.

In summary, on these two points, if we are to consider the compromise proposal as a starting point for discussions, manufacturers need two things. We need to tightly define the uninsured category and we need to eliminate the States' unrestricted access to low-cost vaccines.

Now I would, if I could, propose an alternative approach which I think is worth considering. The problem, as I have stated, is that manufacturers have with your compromise proposal the manufacturers face an inability to either estimate accurately or to control the amount of vaccine sold at negotiated prices.

Manufacturers would probably find it a lot easier under a system in which the Federal Government purchased at a negotiated price a specified amount of vaccine. And this should be consistent with the administration's new resolve to focus on Medicaid and the uninsured. We would propose that the Federal Government purchase enough vaccines to cover children at 200 percent of the poverty level.

The vaccines would then, as we see it, be distributed either with or without a contribution of State funds because, frankly, the distribution of vaccines for us has become a patchwork affair, with some States taking all the vaccines off of the Federal contract and others finding their needs essentially unmet.

Perhaps the Federal Government, which essentially encouraged or allowed this variability among States in the amount of vaccine produced could actually sort it out and allow those who should be entitled to a discounted vaccine to get that vaccine. And honestly, that was the intent, as we understood it, of Section 317 of the Public Health Service Act.

Now aside from Federal purchase, Lederle-Praxis will, of course, continue to provide services to the private sector, including our public pledge to freeze prices for 1993 and to hold any increases for 1994 at the consumer price index.

Now, whether this translates to savings to consumers depends on physician fees as you pointed out in your own comments earlier.

What concerns me about the process we are in right now is the absence of careful deliberation of options and the potential impact on what really has been a truly successful program.

Last year, if I may——

Senator RIEGLE. Please, go ahead.

Mr. SALDARINI [continuing]. You had, I believe, witness after witness come in front of this committee and go through the deficiencies in the Medicaid program as a major reason for low immunization rates. This year, in stark contrast to what we observed last year, vaccine prices are the primary emphasis and it would seem that universal purchase or some variation of it is a panacea for all elements of the immunization effort.

I am concerned that we are moving too fast without taking into account the consequences of our actions. I hope that this committee will find the views of those of us who develop and manufacture these vaccines helpful and allow us to work with you so that we can reach a compromise that would allow a free market place to prevail and yet still serve those who are truly in need, which we are all interested in doing.

Thank you very much.

Senator RIEGLE. Before we go to your colleague, let me just say I am looking for the best answer we can find. So I take your comments in the spirit in which you present them. I think the example you use of Medicaid deficiencies last year and price problems this year, I think we have both those sets of problems and more.

So I do not think it is a matter of either or or just one problem now having sort of gone away or been replaced by the other. You were here earlier and you heard the case of the young woman, the mother from Michigan. My sense is from just all the work we have done and the number of people that I have talked to in Michigan, that we have a lot of people in that situation.

In other words, they may have partial insurance coverage, but they are not covering immunizations. They do have a primary doctor relationship established. The cost of getting through the whole series of vaccinations when you take both the cost of the vaccines, whatever the add-on is that the doctor is applying in order to give the vaccines, and then if there is a well-baby aspect to it as well—the bottom line is it has become very expensive for people to go through the drill, especially if you have more than one child. We have in effect now sort of a two-tier, at least a two-tier pricing system. I think if we could probably look at all of the pricing that is being done through private physicians we would probably see there are multiple tiers or there are a lot of different pricing variation in some range.

But with respect to what it costs to get it done there, say, on average versus what the cost is in a private clinic or somebody who shows up to get the help there, it is very different.

So in a sense I suppose one could say that one is in some fashion subsidizing the other. Would that not be probably a correct statement to make?

Now, you can argue whether we should be doing that and whether insurance, if it is going to be there, should pick up something as fundamental as an immunization anyway. But that is sort of a side issue.

I think one of the questions is how do we go about sort of leveling off the cost here in some way and getting it down to the point where it is sufficient for you to be able to recoup your costs, do the research and development, look for new answers, you know, package these vaccines in new ways such as you are doing.

You talked about three that have coming down the line in the last few years. How do we go about structuring this so that we try to get away from some of these sharp pricing variations when underneath it all we are really talking about is protecting kids from diseases and you have obviously devoted your life in large part to accomplishing that end and I appreciate the fact that you have, just as the doctors who were here earlier playing their part.

But how do we go about getting not just the kids on Medicaid or those who are 200 percent of Medicaid, but all the kids in the country vaccinated at the lowest cost that really still gets the job done for you without having this patchwork all over the place that we can say, is the nature of the system we have.

But is that the best we can do?

Mr. SALDARINI. Well, I think those comments are very well considered. If I may comment on the young lady who was speaking earlier; she is obviously covered by a plan, but the plan does not cover immunization insurance.

Within the framework of the compromise proposal, I believe that you were going to—or at least I heard Secretary Shalala mention that you were going to—mandate that insurance companies which are currently covering immunizations would not be allowed to drop that coverage.

Perhaps a more appropriate way would be to say that all companies should be required to cover immunizations as a core benefit. Then this young lady would have seen her private physician and that would have been very helpful.

Let me give you an example. I may have mentioned this at the last hearing, so please forgive me if I am being redundant. But my own company spends $4,000 per employee per year on medical insurance of all kinds.

Senator RIEGLE. Right.

Mr. SALDARINI. And first dollar coverage, no co-pay, no deductible, costs my company an extra $35 per employee. I remember this young lady saying she spent $300 a month in medical insurance.

Senator RIEGLE. Right.

Mr. SALDARINI. It would be best if within that framework, there could be a mandated benefit which would expand her coverage so that well-baby care, well-child care, immunization costs—the actual costs of the product, as well as the costs of the doctor to administer the product—can be covered for roughly $35 per person.

Now in the framework of managed competition, which I think is where the Clinton administration has certainly indicated it wants

to go, this seems to fit. If we could get immunization insurance mandated on a national basis, that covers the families who are currently uninsured for immunization benefits. About half of those who are insured have no coverage for immunizations.

But they are not Medicaid eligible and are not uninsured. So it is a significant number. And by simply changing your mandate in your proposal from one that keeps people from leaving to one that requires immunization on coverage, you may well serve your needs and still target your immunizations to those who are truly in need.

Sorry, that is a long winded answer but I am trying to address your question.

Senator RIEGLE. No. I appreciate the fact you are and I did not consider it a long winded answer. I think we have to take the time that it takes to lay these things out. So, no, I welcome your response.

[The prepared statement of Dr. Saldarini appears in the appendix.]

Senator RIEGLE. Do you want to go ahead and make your comment now, Doctor?

STATEMENT OF JEAN-PIERRE GARNIER, EXECUTIVE VICE PRESIDENT, SMITHKLINE BEECHAM PHARMACEUTICAL, PHILADELPHIA, PA

Dr. GARNIER. Before I do I want to stress the importance of the last point that was discussed. I think this is the core of the debate of the new compromise. And, of course, we have not seen the final text, but from what we have understood it to be, this is really the core of the debate, so I wanted to emphasize an important point of the discussion.

Senator RIEGLE. Please do.

Dr. GARNIER. Let me go quickly through a short statement if I may, Mr. Chairman. My name is Jean-Pierre Garnier, executive vice president of SmithKline Beecham. SmithKline Beecham is a transnational health care company with principal activities of the discovery, development and manufacture of pharmaceutical, vaccines and other health care goods and services.

Now as far as the vaccines are concerned, we are a major supplier of polio and measles vaccines outside the United States and we market Engerix-B, a biotechnology-derived Hepatitis B vaccine in the United States and around the world. Every second of every day, 15 people worldwide are inoculated with one of our vaccines.

We consider our R&D effort in vaccines second to none. We are working on Lyme Disease, Aids, and we recently introduced the world's first hepatitis A vaccine in Europe, and we presently plan to offer a full range of pediatric vaccines in this country.

Today I would like to submit my written statement for the record and turn to a few key issues relevant to the ongoing discussions on vaccine legislation. First, a general observation. We understand that the current compromise legislation to be considered in the house will focus on expanding access to vaccines for those who cannot afford them rather than a universal purchase system.

We at SmithKline Beecham believe that a focus on the population that cannot afford vaccines, combined with a strong legislative framework for improving our vaccine infrastructure is the most

cost effective way of achieving real increases in immunization levels.

Most importantly, unlike a universal purchase system an expanded access framework has the benefit of ensuring a private market that will help support research of future vaccine products as well as continued investment in maintaining vaccine production capacity.

Obviously, we will have to wait and see the details of any expanded access compromise. We must ensure that we are not sweeping into the plan a large population of persons who actually can afford vaccines or have adequate insurance.

Moreover, we must not provide an incentive for insurance companies to drop immunization coverage. Indeed, and I think this is a key point we were discussing earlier, we should require all private insurers to, as is the case in Pennsylvania, incidentally, to provide full coverage for recommended childhood vaccines as well as other preventative care services.

Senator RIEGLE. Could I just ask you at that point, if I may interrupt, when you look across the spectrum of health care initiatives and you are in the health care business, is there anything out there that is any more directly cost effective on a broad scale than say an immunization? I mean, in terms of the cost versus the value of avoiding the illness and the treatment for the illness.

Isn't that about the most effective single step we could take in terms of anything like a universal health care protection?

Dr. GARNIER. Mr. Chairman, absolutely. On top of that I think it is fair to say we have heard a lot about vaccine costs and I cannot comment on any of the statistics which represent it because they certainly did not involve SmithKline Beecham products.

As you recall, we are fairly new on the scene. But over the last 3 years, as Dr. Katz documented, we have actually contributed to a decline, a steep decline of the price of hepatitis B vaccine in the United States. This is the results of market forces.

Now if you look at the cost of the hepatitis B vaccination, I mean, we are talking about—let us be honest here—we are talking about $27—$27 to cover you for the risk of liver diseases and cancer in 5 percent of the cases of people who catch hepatitis B. This is a product that actually prevents cancer of the liver in a small but meaningful number of cases. There are 350,000 hepatitis B cases in the United States every year; 2,000 of them will contract cancer.

I think we have to put things in perspective here. Let's look at the price of many items outside the vaccine arena. I am very surprised not hearing any comment, for instance, on the relative costs of vaccines and the cost of actually administering the vaccines in a private setting.

The vaccine cost is a small part of the entire immunization process and yet the entire attention of this panel has been on the smaller part of the problem. I do agree with you that some patients are really finding it difficult to get immunized by their private physicians. I find this unacceptable.

But the reason why the economics work against the patient have very little to do with the cost of vaccine. The cost of vaccine is about one-third to one-fourth of the total cost.

Senator RIEGLE. Well, shed a little more light on that. What knowledge or information do you have about the build up in cost unrelated to the price of the vaccine that gets built in to the process through a private doctor's office?

Dr. GARNIER. Well, I suspect in your particular case when you mentioned the vaccination of your child, if you were now to compare the $75 fee, plus the $54 that was charged to you for the price of the vaccine and added it all up, and if you were now to compare that to what the vaccine manufacturer received as revenue, you would find it is probably in the 20 percent-range of the total cost.

Senator RIEGLE. Actually, as a matter of fact, I tried to do that.

Dr. GARNIER. We can help you to do it. This happened to be a different vaccine from the one I referred to.

Senator RIEGLE. No, I understand.

Dr. GARNIER. But we will be glad to help you to establish that fact. I think that is a very significant fact.

Senator RIEGLE. It was not lost on me. We have a sheet here that purports to list vaccine prices as of June 19, 1992. So I was checking the price on this summary of the MMR and the HIB shots in terms of both the dose through the CDC as a public price and then also in a private sector price.

I could see a substantial add-on. So I am interested in that. I am not just interested in the question of what the vaccine cost is.

By the same token, in the insurance issue as to whether or not you are insured or not is a highly relevant issue; and I think it is important and we have all sort of agreed on that today.

I think the tiering system on price, however, is still left out there and we have to think through the question on something as fundamental as this. You have built in sort of a two-tier pricing system in any case. When you have bulk purchase and you have public purchase, by in large you are selling your vaccines at a lower price based on volume and on that kind of pressure than you are when you are selling it batch-by-batch to doctors or however it is making its way out to the private doctor's offices.

I assume, I do not know how you go through your pricing operations, but on the face of it it would appear that one provides some kind of a cross subsidy to the other. Otherwise, if the public sale is profitable, if it is profitable in and of itself, then the sale on the private sector side is even more profitable.

Now I have not heard anybody assert that the vaccines that are being sold through the public sector are being sold below cost and are, therefore, being sold at a loss, being made up for by profit over on what is distributed through the private sector.

I gather a profit is being made in both sectors, a lesser profit being made on what is sold through the public channels, a larger profit in terms of what is being sold through the private channels. Is that essentially correct or would you want to amend it?

Dr. GARNIER. Mr. Chairman, I would not necessarily conclude that in the case of hepatitis B. First of all the spread between the two is fairly modest. The other aspect is, a sale to the CDC of a very large quantity of vaccine is, in fact, economical for us because it does not require any educational effort with the physicians any cost of distributing to every independent physician.

Therefore, you do have economies of scale. I mean, the sale to CDC is a low-cost sale. The only cost is really manufacturing costs and, of course, some money that you have to set aside for R&D.

So you cannot necessarily conclude that one is more profitable than the other. However, what is clear is the total revenue that is relevant to us. It does not really matter at the end how you get the revenues, but our business has incurred tremendous fixed costs. We have to maintain our facilities under the right GNP principals and R&D is not something that you can turn on and turn off.

You have to commit to long-term research.

Senator RIEGLE. I understand that and I appreciate that point.

Dr. GARNIER. So, Mr. Chairman, it is the usual story. We look at the total revenues and then those revenues have one way or the other, they have to be able to cover those fixed costs and leave us some reasonable return for our shareholders. So that is really the way we look at it.

The reason why private market prices have not shot to the ceiling is very simple. There is competition in the market place and, therefore, there is a limit. It is very demand, elastic.

Senator RIEGLE. Well, the reason there is not, I was talking to my wife about this, and, you know, gathering information from our experience and from many others, and if you have a primary doctor relationship and you are going in and you are getting a child vaccinated, if you can afford to pay for it, and it is not covered through an insurance program and you can afford to pay for it, I think most people go ahead and do that.

They do not necessarily decide, unless they are really severely pinched financially, and the doctor says it is going to cost this much, that they then say, no thanks, I will not do this; and then they try to go through a public clinic.

So I think an awful lot of people are sort of swept into the circumstance that they are in without necessarily understanding the footing they are on in terms of what their cost choices are.

What I am interested in figuring out from the point of view of the public interest, and maintaining a viable, strong, private sector vaccine pharmaceutical industry, if you will—that is, if we want to get everybody vaccinated, and that is what we want to do from a public interest point of view, we want to get all the kids through the routine of shots on time by the time they are two and so forth, how do we get that done to get the cost down to the lowest feasible level it can be that still is sufficient to allow you to stay in business and earn the profit and the research money that you need. It eliminates sort of the bouncing around of people in the cross subsidization through a tiering pricing system.

I mean, what is the most efficient way to get the maximum amount of vaccine out there and into each and every kid so that we overcome some of these problems. Because the data that we are seeing show that it is not all just people not understanding the problem.

And a lot of the people absolutely do understand the problem and a lot of the problem is financial for a lot of people, quite frankly.

But anyway, you were going to make a response. I would like to hear it.

Mr. SALDARINI. I think your focus needs to be on the three things that are very clearly most lacking—education, tracking and outreach. That is a way to get to these kids who are really underimmunized or not properly immunized.

Senator RIEGLE. Yes, but you are leaving one out, in all due respect. And you, yourself, put it in earlier when you addressed the woman's problem from Michigan. If you do not address cost, you want to address it through an insurance coverage. But you cannot list the three and leave the fourth one off.

I mean, when you, yourself, introduced the fourth one earlier, does it not have to go on the list, too?

Mr. SALDARINI. No, it certainly does have to go on the list. But I think you need to address that issue by recognizing that there are other ways to approach that element. One is with immunization insurance. Another one is to try and stimulate physicians to give Medicaid patients a pediatric home.

And to do that you have to increase physician reimbursement from Medicaid substantially.

Senator RIEGLE. Right.

Mr. SALDARINI. So that there is an incentive for the physician, who has overhead and fixed costs just as we do, to see Medicaid patients.

And in terms of——

Senator RIEGLE. So what would the items be then that you would put on the list?

Mr. SALDARINI. We certainly think that you need to consider a mandated core benefits package that includes coverage. This has been worked on in individual States. Some States have passed it. I believe Pennsylvania is one of those States.

But a core benefits package that covers well-baby, well-child, vaccine costs, plus vaccine administration is one. I think very definitely you have to go after a level of Medicaid reimbursement that makes it satisfactory for a physician to have a Medicaid patient in his or her office as opposed to having them move to the public health clinic where the issues of access and education and tracking then start to play, the other portion of your four quadrant analysis.

So I think there are several things that can be done. But I think the main point that we are trying to stress is that in order for us to continue to evolve the development of research as we have so far over these past 10 or 12 years, we are going to need to be able to have profits that are reinvested into the business and allow us to continue to grow and move to the next century.

There is a lot coming in the next century and even between now and the next century.

Dr. GARNIER. Mr. Chairman, may I give maybe a complementary answer, too?

Senator RIEGLE. I want you to do that. Could I insert one thing before you do?

Dr. GARNIER. Sure.

Senator RIEGLE. Because you may want to add this to your response. That is, I do not think it is just a Medicaid issue, and that is part of the problem. Even Senator Danforth when he was here was talking about setting a standard that it would be 200 percent of the level of poverty, which is an acknowledgement that you just

cannot use these poverty line cut-offs. It does not really get to enough of the problem.

The data that we have says that some 70 percent of the 2-year-olds that are not immunized are above 100 percent of poverty. So the problem does not divide neatly into the poor and the not poor. It is far more complicated than that.

So in any event, let me hear your response and maybe that will relate to it.

Dr. GARNIER. Mr. Chairman, we made a proposal at your last hearing which was in four points. I am not going to repeat it in great detail. But I want to add one more element.

I think that we have to look at the market as a structural element and our proposal was to make sure first of all that poor children would get the best possible price on the vaccine that is possible. That is not the case today.

Medicaid reimburses the cost of the vaccine in a number of States at a fairly high price. That certainly does not help the local effort to increase outreach and so forth. The money can only be spent once. So we were advocating——

Senator RIEGLE. How could they do that? I mean, why would the people doing the buying be foolish enough to do that?

Dr. GARNIER. Well, there are a number of reasons but one of them is it is not easy necessarily to benefit from the CDC prices if you do not have your own distribution system and so forth. We would make it easy in our proposal so that all the Medicaid programs benefit from the CDC price.

So first I would provide a saving to the States. They can reinvest this money into paying higher fees as my colleague was suggesting for the physicians, so that the physicians are not turning back the children to the public clinics.

At the same time, we are spending our money on public clinic in terms of the new proposal to make it more convenient for the parents. At the same time the technology is giving us hopes because we are reducing the number of injections. This is going fast now. There are several companies, including mine, ready to come on the market in a couple of years with a clearly simplified schedule.

There is no one element that is going to resolve it. All of those elements are important in my view. Now in the compromise we are getting closer to this model. But we still have not structured the market in a way which is clearly defined. And if I ever get a chance to complete my testimony today, I would like to come back to that point.

Senator RIEGLE. Please make that point right now because I am willing to listen.

Dr. GARNIER. I will be very short. But I do want to address a couple of other points. One of them, again, is this problem of the private insurance. I mean, we are fairly close to the point where every American will be entitled to immunization. And we should not lose sight of that.

This is going to be an important element that refers back to this particular legislation. I still consider, and Dr. Katz reminded us of this, that because of the remarkable cost efficiency of preventative immunization, it is actually good business for private insurance companies to encourage immunizations and reimburse them.

This is a way to make money as an insurance company. I think we should really try to lean on the insurance industry so that they voluntarily decide to include this immunization benefit right now. It is good business because those children vaccinated between the ages of zero and two will not end up in the hospital at a considerable cost.

In all likelihood, those children are still insured with the same carrier because we are talking about very few years where we are closing the window here. So I cannot comprehend why there is not much more of a push—a public push, a political push—to get the insurance company to accept that.

If we were to achieve that goal, Mr. Chairman, we would then have resolved one of the difficulties that still exists with the compromise because we would have clearly defined a population that is going to stay and would have no motivation to come out of the private market and leak into the public market.

And at the same time if you follow the SmithKline Beecham proposal, you will be able to realize a savings by restructuring the public market and making sure that the lowest possible prices are paid by the Federal Government. This is a very effective way to maximize taxpayers' worth.

Now this being said, I would like to come back to two minor points that have been included in the last text we saw, which is probably not the last text which was issued. We want to talk about the expanded access compromise in the sense that there is a clause here concerning multiple suppliers. I am not going to spend much time on this.

I think it is a given that stability among the number of manufacturers would allow us as a new company to come in and it would make sure that the result really will be the concentration of the maximum marketed products and the elimination of a risk of shortage. We should not lose sight of this and I was very gratified to see that this text is present in the compromise and just needs some strengthening.

In terms of the sales of excess vaccine by the government, this is a technicality, but it is not unimportant, another key issue is a provision reportedly being considered that would permit the government to dispose of excess quantities of vaccine that are nearing expiration dates by dumping such vaccines on the private market.

Essentially, this would provide an incentive for excess purchases by the government that would undermine the private market for vaccines. A clear alternative to this provision is found in a common practice in the private market in which companies maintain a return policy in which newly produced vaccines are exchanged for the expired products, within reasonable limits.

In other words, we should modify that provision and make it very easy for the center to get replacement on the vaccine that have expired. We would commit as a company to replace those vaccines free of charge if they come to expiration as part of our contract with the State.

Senator RIEGLE. Would that be an industry-wide feeling?

Dr. GARNIER. Well, they have to answer for themselves.

Senator RIEGLE. But you would be prepared to do it?

Dr. GARNIER. We would be ready to do it.

Senator RIEGLE. All right. Why don't you go ahead.

Dr. GARNIER. With regard to distribution of vaccines, some have suggested that the private replacement program model be used. This inefficient model involves what is essentially a consignment program that gives one manufacturer a de facto monopoly over the distribution of vaccines for a given population. Such a monopoly would inevitably expand to the private market and result in higher vaccine costs.

Moreover, if the government is to be purchasing and distributing vaccines for those persons who cannot afford them, the replacement program model is simply incompatible with that concept.

Finally, Mr. Chairman, let me note that if we are to provide vaccines for an expanded population, we should provide all vaccine that are recommended by the American Academy of Pediatrics. The inclusion of such vaccines should be a presumption in this legislation, perhaps subject to a contrary determination by the Secretary.

Moreover, all such vaccines should be covered, and I think that is anticipated, by restoring the vaccine injury compensation program.

Thank you for the opportunity to provide our views on this important legislation. I would be happy, of course, to address further questions.

Senator RIEGLE. Gentlemen, thank you. It has been a long day. We are going to conclude the hearing at this point. It has been very helpful to us and we appreciate your participation.

The committee stands in recess.

[Whereupon, at 5:20 p.m., the hearing in the above-entitled matter was recessed.]

APPENDIX

Additional Material Submitted

Prepared Statement of Louis Z. Cooper

Mr. Chairman, I am Louis Z. Cooper, M.D., Director and Professor of Pediatrics at St. Luke's/Roosevelt Hospital Center in New York City, here today representing the American Academy of Pediatrics. As pediatricians, we are dedicated to providing comprehensive care to all children and recognize childhood immunizations as one of the most effective of all preventive health measures. We commend you on your long-standing commitment and leadership in removing all barriers to childhood immunizations.

The Academy views S. 733 as a complete and aggressive strategy to positively impact on the plight of young families trying to immunize their children against preventable childhood diseases and urges its passage, along with S. 732.

At the joint hearing of the the Senate Committee on Labor and Human Resources and the House Subcommittee on Health and the Environment on April 21, the case was clearly made for the need for a national immunization tracking and registry system, improved outreach and educational efforts and amendments to the National Vaccine Injury Compensation Program. The issue of federal purchase of all vaccines, although raised at that time, was appropriately left to the purview of this committee.

At that hearing, Academy witness Dr. Ed Marcuse made the analogy that our nation's childhood immunization program is like a car with four flat tires, the tires being access, cost, tracking and outreach. As stated so well by my colleague, a car with four flat tires isn't going to go very far very fast until we fix all four flats. So let's all roll up our sleeves and fix the last flat---cost.

Recent articles in the media have raised serious questions on why America, with its scarce fiscal resources, should subsidize vaccine costs for middle and upper income families---that the immunization of children is the parent(s)' responsibility. However, the costs of parents' failure to fulfill this responsiblity is borne by society---in costly outbreak control, in hospital and medical bills, in special education costs for the care of children who suffer the sequelae of vaccine-preventable disease or in the loss of a precious young life. It is time that we, as a nation, accept that the immunization of all our children is a public health responsibility, similar to ensuring a safe water supply or sanitary sewage disposal.

This is not to say that immunizations should all be given in public clinics. Far from it. Ideally, immunizations should be part of basic ongoing, comprehensive health care delivered in the child's medical home. Responsibility for immunizing our children is shared between the public and private sectors and both are needed to serve children.

We have partially accepted the idea of public health responsibility by recognizing the need to embrace the tracking, outreach and access initiatives proposed by the Clinton Administration, but policy makers appear to have stopped short of accepting the fiscal responsiblity. Cost is that fourth wheel and it bears careful review by this committee.

From the pediatric perspective, it is important to look at the cost issue from three sides: the first is what makes up the cost; the second is who pays the cost; and the third is the impact on child health in general.

Vaccine costs in the private sector are considerably higher than those purchased for the public sector. (See Appendix I) This cost differential is at the root of the move toward universal purchase at the federal level since it threatens the balance between the private and public sectors. With an increasing trend toward the public sector, can the vaccine market be sustained at the CDC prices? Eleven states took advantage of this cost savings, but further state efforts were halted by the manufacturers. (See Appendix II) The manufacturers stated that any further disruption of this public/private balance would impede research and development of new vaccines and that if the private market were removed, the public prices would increase.

While I have no specific information on all the factors that make up the base price of a particular vaccine, I can comment on the excise taxes and administrative costs. The excise taxes were imposed by law in January, 1988 and are currently $4.56/dose DTP, $4.44/dose for MMR and $.29/dose for OPV. These taxes are currently levied against the manufacturers, but are passed on to the consumer. With respect to vaccines, the consumer is either the parent(s) or public health clinic. The Academy supports the continuation of these taxes as their interruption has placed the vaccine compensation system in limbo. They have added to the overall cost of complete immunizations, but if one analyses the private price of vaccines from 1982-1992 in terms of price increases, excise taxes and new vaccines, only 16% is due to the excise tax.

The cost of giving the vaccine is borne by both the public and private sector providers. These administration costs are significant and include time costs, overhead, medial supplies, reporting forms, counseling on benefits and risks, and record maintenance. (See Appendix III) In today's medical economic world, practitioners cannot absorb these costs. Administration costs vary, depending on region and locality. However, in states that have universal purchase of vaccines, the administrative cost is fixed. The state of Washington, for example, allows for a $10 administration fee. The contribution of administration costs to immunization is unknown, since such data does not exist across a community, much less the country.

Are immunization rates better in states that have universal purchase? My impression is yes and that a trend does exist

for the better, but none of the state data are ideal and, as noted above, other factors play an important role. Only two states, Massachusetts and New Hampshire, include all recommended vaccines in their program. However, it is clear that countries with universal delivery and tracking systems do far better than our current best efforts in this country. It is ironic that of the eleven states that at least have a partial universal purchase plan, most are in the New England area where, in general, the median income is higher than the national average.

It is also important to take a look at the public/private share of the population in states with at least some universal purchase agreement. There is a very high participation rate of private physicians in these programs. King County in Washington state has over 70% of children immunized in the private sector and New Hampshire immunizes 95% in physician offices.

The question of who pays is a sensitive issue, particularly for the middle class. Since immunizations are often not covered by health insurance, they must be paid out of pocket, causing financial hardship to many working and middle class families. Out of pocket costs of vaccines drive young parents away from their usual private source of care in to already over-stretched public clinics. Referral to clinics is usually for the vaccine(s) only, not as part of comprehensive health exams. Sometimes this leads to a delay in vaccinations until school entry where state laws require that children be immunized. From the view of parents whose budgets are already stretched to capacity, a delay in immunizations is the rule rather than the exception. The appalling mortality and morbidity rates for our under five population detail the gruesome human and societal costs for children who were forced to wait.

The cost of vaccines impacts negatively on our ability as pediatricians to immunize infants and children, which results in missed opportunities when referrals are made. The reasons for referral are families that are uninsured or underinsured (vaccines not covered by insurance) or Medicaid-eligible families where Medicaid does not cover the cost of vaccines/or administrative costs. Immunizations should be given on a timely schedule and within the context of a well-child exam.

In a 1992 survey of our membership, we found that the most important reasons for referral for immunization, by a substantial margin, were those related to the cost to the patient. Well over half of the respondents indicated that patient concern about cost (54%) or request for referral due to cost (64%) were very important reasons for referral. By contrast, cost to the pediatrician (26%), unavailability of vaccine (9%) and concern about liability (3%) were much less frequently rated as very important.

The fourth tire is an expensive one, but one that cannot be ignored. Sadly, the rising costs associated with immunizing children, coupled with access barriers, has altered the public's perception of the risk/benefit of immunization services. In fact, for many parents, disease prevention has become a much lower priority than needs of day-to-day existence. We, as a nation, are paying an even higher price for declining and/or incomplete immunization rates.

By moving to universal purchase of vaccines, along with the creation of a universal tracking system, improved access to delivery sites and more agressive outreach, I believe we can accomplish the following:

1) All financial barriers to vaccines will be removed.
2) A fair market price can be set for vaccines that does not compromise vaccine research and development.
3) Childhood vaccines for all children will be part of ongoing comprehensive health care with high participation rates from the private sector.

With a strong national policy set on this four-pronged approach, death and disability associated with illnesses which are preventable with vaccines should not occur in this country. And as difficult as budgetary choices are, we must not shortchange our children. Simply put, when immunization rates decline, the incidence of diseases increases. To compromise on what we know is needed is gambling with the lives of our children.

Appendix I

COST FOR FULLY IMMUNIZING A CHILD IN THE PRIVATE AND PUBLIC SECTORS

	PRIVATE			PUBLIC		
VACCINE	1982	1991	1992	1982	1991	1992
5 DTP	$ 1.85	$49.85	$50.20	$ 0.75	$31.25	$29.93
4 OPV	$11.00	$37.80	$39.64	$ 1.92	$ 8.00	$ 8.38
2 MMR	$10.44*	$50.58	$50.58	$ 4.02*	$30.66	$30.66
4 HiB		$58.20	$60.52	$ 6.00	$20.64	$21.46
3 Hep.B			$32.12			$21.72
TOTAL	$23.29	$196.43	$233.06	$ 6.69	$90.55	$112.15

* Second dose of MMR not recommended

Source: U.S. Centers for Disease Control

Appendix II

VACCINE ADMINISTRATION COST COMPONENTS

- Printing of Vaccine Information Pamphlets (VIPs)
- Ancillary supplies (e.g., needles, syringes, alcohol, swabs/cotton balls)
- Nursing costs (e.g., pulling charts and recording, administrating vaccine, acquiring informed consent)
- Medical waste disposal (e.g., needles and syringes)
- Recordingkeeping/abstraction (e.g., information for schools, camps, colleges)
- Appointment scheduling (e.g., information for schools, camps, colleges)
- Storage (e.g., refrigeration, temperature gauging device, recordkeeping for high/low temperature)
- General office overhead (e.g., rent, utilities, liability insurance premiums for coverage in excess of vaccine compensation legislation)
- Employee training (e.g., annual OSHA training for bloodborne pathogen standard, materials and time devoted to vaccine handling training)
- Forms for vaccine recordkeeping including informed consent
- Counseling parent(s) or guardians on benefits/risks of vaccines
- Record keeping in compliance with National Vaccine Injury Compensation Program

With passage of Comprehensive Child Immunization Act:

- Administrative costs associated with National Registry/Tracking system

STATE FUNDED UNIVERSAL VACCINE PROGRAMS

(as of 4/30/93)

STATE	BILL NUMBER	STATUS	UNIVERSAL DISTRIBUTION PROGRAM	BULK PURCHASE FOR MEDICAID	COMMENTS
ALABAMA					
ALASKA			X		
ARIZONA	HB 2254	Enacted 1992		X	Original universal plan amended to Medicaid patients only.
ARKANSAS					
CALIFORNIA	AB 3354	Enacted 1992		X	Distribute to private providers for Medicaid patients.
	AB 3351	Enacted 1992			Savings from bulk purchase program to be used to increase private providers fees.
COLORADO	HB 1208	Enacted 1992	X	X	Funding for Medicaid patients only.
CONNECTICUT	SB 342	Enacted 1991	X		Program existed previously. Law codifies it and adds a second measles vaccine and Hib vaccine to the state supplied program. Requires immunizations for day care attendance.
DELAWARE					
DISTRICT OF COLUMBIA					
FLORIDA					
GEORGIA					
HAWAII	HB 1899	Introduced			Universal distribution program.
IDAHO		Enacted 1990	X		
ILLINOIS				X	
	SB 476	Defeated in Committee			Universal distribution program.
INDIANA					
IOWA		Adopted 1992	Pilot project in 1 county.		By regulation.
		Began 1992		X	
KANSAS				X	
	SB 92	Introduced Jan. 1993			Universal distribution program; provider could charge "reasoneble" administration fee.
KENTUCKY					
LOUISIANA	HCR 29	Adopted 1992		Pilot project in 1 county.	
MAINE			X		

STATE	BILL NUMBER	STATUS	UNIVERSAL DISTRIBUTION PROGRAM	BULK PURCHASE FOR MEDICAID	COMMENTS
MARYLAND					
MASSACHUSETTS		Began 1920	X		
MICHIGAN			X		State manufactures and distributes vaccines to public and private providers.
		Began 1987		X	Vaccines replaced through health department.
MINNESOTA					
MISSISSIPPI					
MISSOURI					
MONTANA					
NEBRASKA	LB 431	Enacted 1992			Childhood Vaccine Act. Pilot program that tracks immunization rates, encourages cooperation between public and private providers.
NEVADA					
NEW HAMPSHIRE	SB 72	Enacted 1991	X		Program existed previously. This appropriation provides for 2nd measles and HiB vaccines. In 1992, added Hepatitis B to program. Insurance companies pay into the state distribution program.
	HB 74	Enacted 1991			Created Vaccine Purchase Fund.
NEW JERSEY					
NEW MEXICO					
NEW YORK					
NORTH CAROLINA	Budget	Introduced			Universal distribution program.
NORTH DAKOTA	HB 1404	Failed			Universal distribution program.
OHIO				X	
OKLAHOMA					
OREGON					
PENNSYLVANIA		Enacted 1992		X	Pilot project with 20 medical assistance providers. To expand statewide in 1994, beginning in counties with the lowest immunization rates
PUERTO RICO					
RHODE ISLAND	HB 7276	Enacted 1991	X		Program existed previously. This appropriation funded by an insurance tax and provider licensing fee. Provides for 2nd measles and HiB vaccines.
SOUTH CAROLINA					
SOUTH DAKOTA			X		
TENNESSEE	SB 1454	Introduced Feb. 1993			Universal distribution program; vaccines as recommended by AAP

STATE	BILL NUMBER	STATUS	UNIVERSAL DISTRIBUTION PROGRAM	BULK PURCHASE FOR MEDICAID	COMMENTS
TEXAS		Enacted 1991		X	State distributes vaccines to private providers and on a trial basis provides extra vaccines for children < 200% of FPL.
	HB 916	Introduced			Universal distribution program.
UTAH					
VERMONT			X		
VIRGINIA					
WASHINGTON		Began 1990	X		Part of governor's budget.
WEST VIRGINIA	SB 38	Died in Comm.			Universal distribution program.
	SB 2525	Died in Comm.			Provides Hep B to certain people.
WISCONSIN		Began 1992		X	
WYOMING		Began 1978	X		

PREPARED STATEMENT OF SENATOR DAVE DURENBERGER

Mr. Chairman, I join all the Senators here today in our strong commitment to a healthier America and to prevention and well-baby care. There is absolutely no doubt that early childhood immunization is essential to a successful strategy for improving the general health of America.

We are fully committed to immunization. Indeed, we are very long on commitment. But while it is true that commitment often leads to answers, I would caution at this point that *commitment is not a policy.*

There is a health policy expert at the University of Minnesota named Bryan Dowd, who says the problem with health policy today is "we have 1000 answers and no questions."

And I am afraid that, despite the commitment of its authors, the bill we are considering has not asked the right questions.

The centerpiece of the Administration's revised bill is still federal purchase of vaccines, where the federal government will buy vaccines each year and distribute them to states. But, the *question* is: Is the cost of vaccines the real barrier to immunizations? Is there evidence that this "answer" will solve the problem?

In other words, will the investment of an estimated 8 million dollars in the purchase of vaccines really work? I have my doubts.

There are so many other factors that affect the immunization levels. Many of those barriers are cultural. Some are due to lack of education, and some to infrastructure problems like limited clinic hours, long waits, and lack of transportation. The fact is that every community is different, and that strategies to overcome these barriers depend on understanding the people in those communities. We need to allow state flexibility to address these issues, community by community. Federal dollars simply won't solve these problems.

Last session, I supported efforts by the Appropriations Committee to expand funding for immunization grants to states. We raised appropriations for immunizations under this program to $341.78 million, an increase of $45.08 million over FY 1992.

These grants allow states to determine what barriers really exist to access in their communities. In other words, states have the flexibility to ask the right questions, and then come up with appropriate solutions. Under this program, the CDC awards grants to states and local governments to develop and implement Immunization action plans (IAPs).

Minnesota has received a grant of $900,000 to develop an action plan and implement an improved vaccine delivery system. Even in Minnesota—which is a rel-

atively homogeneous state—there are tremendous variations among communities in immunization rates, and the causes are as variable as the solutions.

Senators Danforth, Kassebaum and I have introduced legislation that would provide an additional $200 million to states for community-based Immunization Action Plans, or IAPs. These IAPs fund locally-based assessment and outreach programs. This kind of funding enabled Minnesota to identify pockets of the state population where there were low rates of immunization, and to set up appropriate programs to address the needs of these populations.

Our bill also authorizes optional grants that fund the development of state and local immunization tracking registries. The grants address the substantial issues of privacy in setting up such registries.

Some states like Minnesota, and localities like Philadelphia, have already done assessments under the IAP grants, and have identified barriers to immunization—particularly among Medicaid recipients. Our bill uses this kind of information to give states the flexibility to improve the Medicaid program.

It would also permit states to establish a vaccine replacement program to insure that Medicaid children get vaccinated when they are in their doctor's office. As has already been demonstrated in Virginia, this kind of flexibility allows states to save on Medicaid costs.

Wise policy dictates, and experience supports, a program that allows states to use all the necessary tools to raise immunization rates without throwing resources into communities that do not need these funds. We must concentrate our efforts where they can do the most good. We simply do not have money to waste.

There is really only *one* basic question, and it is this: What is the real goal here? The answer is: healthy children. What I am concerned about is that we will fixate on immunizations rather than on the whole child. Will we spend vast resources to raise immunization rates from 55 to 75 percent, for example, but overlook the child's well-being? A child's health needs and a child's human needs are much more complicated and important. We are going to need an intelligent commitment to public health and healthy communities if we want to reach our goal.

I look forward to hearing the testimony that will be presented today. I also look forward to asking the questions that will help us produce the best *answers.* We don't need and can't afford wrong answers. Our children are too important for that.

PREPARED STATEMENT OF MARIAN WRIGHT EDELMAN

Mr. Chairman and members of the Finance Committee: I am honored to be testifying before you today about the importance of childhood immunizations and the President's universal immunization initiative. The greatest challenge before us is to provide a head start, a healthy start, and a fair start to all children so they arrive at school ready to achieve and learn the skills necessary to compete in a global economy. Assuring that every child is immunized on time must be part of a national strategy of cost-effective economic investments for children and their families and reform of our nation's health care system.

I have recently had the opportunity to listen to representatives of the poorest countries of Latin America, Africa, and Asia report about their success in raising childhood immunization rates over the past decade. In fact, according to UNICEF's most recent report, over the last decade (1981–1991), immunization rates for infants against measles in developing countries rose from 18 to 77 percent. Yet I am ashamed to admit that, during the same period, American children became less likely to be protected against vaccine preventable diseases. We can not wait one more minute to immunize all children against preventable diseases. As a result of shockingly poor immunization rates, we have just emerged from a measles epidemic that struck nearly 60,000 Americans, mostly preschool children. The epidemic killed 166 children and hospitalized 11 more. We've got to act now.

According to new data from the Centers for Disease Control, just 55 percent of two-year-olds were up-to-date for immunizations in 1991. While vaccination rates were lowest among poor children, nonwhite children, and children in central cities, these data show that the immunization crisis is hitting most of American families. Only 59 percent of white children were up-to-date and just 61 percent of children living in suburban areas were fully immunized. Among children with family incomes above the poverty line, nearly 40 percent did not have their shots on time. *Nonpoor children accounted for two-thirds of all children who were behind on their shots.* Like fire departments, fluoridated water, and street lights, preventing communicable diseases is an essential public service needed by the entire community.

I am pleased that the President and the Secretary of the Department of Health and Human Services have made immunizations a high priority. The President's ini-

tiative is comprehensive. It will increase demand from parents through more education and outreach. It will hire more nurses and open more clinics to rebuild the public health system which has decayed over the past 12 years of neglect. It will create a vaccination registry in every state to monitor our children's immunization status. And it will help financially-pressed lower and middle income parents by creating a universal vaccine assurance system.

The President's initial proposal would have provided vaccines for all children, and we prefer that system. It is the simplest, most effective system, which has worked well in the many countries overseas that have universal purchase—and much higher immunization rates than the U.S. I recognize the budgetary and other constraints that have led the Administration and key leaders in the House and Senate to a system of purchase for Medicaid children and for children who are uninsured or underinsured for immunizations. This universal assurance system—children will get vaccines through their health insurance or through government purchase—can work well for children. The fact that the manufacturers oppose even this proposal shows their ultimate disregard for children's health.

The bottom line is that all of our children must be immunized. The Congress and the Administration must provide our nation's children a purchasing system that assures exactly that.

Universal vaccine assurance is critical for several reasons. Over the past decade, vaccine costs have risen by extraordinary amounts. As a consequence, more and more families cannot afford to get their children immunized at their pediatrician or family doctor's office. A decade ago, there was no significant problem because vaccines were far less expensive. **The cost of vaccines alone to fully immunize a child through the preschool years has climbed from less than $11 in 1977 to over $230 in 1993.** The drug companies say the increase is due to excise taxes and new vaccines, not excess inflation or big profits. But that's only true in part—the cost to fully immunize a child, not including excise taxes or new vaccines, rose an average of 44 percent *per year* between 1977 and 1993. The cost of DTP vaccine, *not* including excise taxes, rose an average of 174 percent per year from 1977 to 1993. The point is that, *regardless of the reason for the big vaccine price increases. middle class as well as poor parents now lack access to affordable immunizations for their preschool children, and we have to make access affordable.*

The increased costs coupled with declining incomes of young families have made immunizations a more burdensome expense. Low and middle income parents are increasingly unable to afford immunizations for their children from their family doctors and pediatricians. A study conducted in Dallas found that **over 70 percent of pediatricians and family doctors referred some of their patients to public clinics.** The overwhelming majority of the physicians cited families' inability to pay as the reason for the referrals. The number of children the doctors referred to public clinics increased nearly 700 percent during the previous decade.

The reliance of middle-income families on immunization clinics has overwhelmed the public health system, leading to waiting lists or turning patients away. During the height of the measles epidemic, clinics in Los Angeles reported families lining up at 6 o'clock in the morning for clinics that did not open until 9 or 10 o'clock. In a California study, **61 percent of public immunization clinic patients had a family doctor or other medical home and would have preferred to have their children immunized at those sources.** In a Texas Department of Health survey, *the **average** income of families going to public clinics was over $25,000 in 1989. The large number of middle income children moving into the public clinics has caused waiting lines and overcrowding at underfunded programs already overwhelmed by growing numbers of poor children.*

The universal vaccine assurance plan under consideration today is a refinement of the universal vaccine purchase and distribution system originally proposed in the Comprehensive Child Immunization Act S. 733. The vaccine assurance plan will provide vaccines to all children who are Medicaid-eligible or uninsured. As under the original proposal, universal vaccine assurance will make sure no child goes unimmunized because his or her family cannot afford the shots. It will decrease missed opportunities to vaccinate and provide an incentive for private physicians to immunize all of their patients.

Two weeks ago, I testified at a special joint hearing of the Senate Labor and Human Resources Committee and the House Subcommittee on Health and the Environment. I was appalled by the intransigence of the vaccine manufacturers' misrepresentation of the causes of the child immunization crisis. Despite protections for their economic interests explicitly written into the proposed legislation, they have persisted in threatening to withhold vaccines from American children if they don't get their way.

They have spread half-truths and untruths about the universal immunization initiative and I want to set the record straight.

Myth #1 is that the immunization problem is primarily among America's poorest children, especially in inner cities.

The fact is that the immunization crisis is a problem among increasingly hard pressed middle-income families. **Only one-third of the children who are not up-to-date on their immunizations are poor.** U.S. immunization rates are shockingly low among children of all income and sociodemographic groups. About 40 percent of white children, and 40 percent of children in suburbs, and 38 percent of rural children, are not up-to-date on their shots at their second birthday.

Myth #2 is that a universal vaccine system would spend too much on wealthy families.

The fact is that the vast majority of families that will be helped by this bill are poor or middle class. Incomes of families with young children are far lower than other groups. **In 1991, 70 percent of all families with preschool children had incomes below $45,000.** Young families (families headed by a parent under age 30) had a median income of just $19,000 in 1990. The refinements to the legislation developed by the Administration will target the vaccine assistance to Medicaid-eligible children and children without insurance coverage.

Myth #3 is that a universal vaccine system will hurt vaccine research and development.

The fact is that the Comprehensive Child Immunization Act requires that the government pay a fair price that reflects not just production costs, but additional **research and development expenses, and profits sufficient to encourage future additional research on new vaccines.** Moreover, the President's FY 1994 budget includes new investments to strengthen vaccine research and development at NIH and FDA. There is no financial disincentive to vaccine research and development in the legislation. In fact, a universal system might contribute to the development of new vaccines because the manufacturers may see increased demand (and increased profits) as financial barriers for families and providers are eliminated.

In 1977, OPV (polio) cost $1.00 per dose. If the price had increased at the general rate of inflation for medical care, the vaccine would cost $3.64 per dose today. Instead, the price increased at a rate of 59 percent per year to reach $10.43. The $6.79 excess (above inflation and the excise tax) costs American families an extra $80 million per year for this one vaccine. We have no way of knowing what that $80 million has bought for Americans other than profits for the manufacturers and expensive ad campaigns against this legislation.

Myth #4 is that the cost of immunizations is not a barrier since children get immunized to enroll in school.

The fact is that **it is far cheaper and easier to get enough vaccines at the point of enrolling in school than to fully immunize a child throughout the preschool years.** Fully immunizing a child through the preschool years requires up to 18 doses at 7 different times. The cost is more than $230 plus administration fees and office visit charges. In contrast, just 3 doses of vaccines which can be administered in one office visit at a cost of less than $50 are all an unimmunized child needs to enroll in most schools. But we must immunize preschoolers to protect the most vulnerable children against childhood diseases and protect against disease transmission. Waiting until school entry causes unnecessary childhood suffering, disability, and death, and costs the health system millions of dollars.

Myth #5 is that states with universal vaccine programs only have slightly better immunization rates than other states.

Most of the "universal" states only distribute some but not all recommended vaccines, so financial barriers to doctors' offices and full immunization remain. For example, Connecticut does not offer HiB and hepatitis B vaccines and Maine only offers DTP and measles vaccine. Michigan only distributes the DTP vaccine manufactured in its state laboratories. Other states like Alaska only offer vaccines to private physicians in remote areas.

Myth #6 is that the President's immunization plan does nothing to improve the delivery system to immunize children.

The fact is that **the President's plan has a number of components, of which vaccine purchase is just one. The President has proposed an additional $326 million in the FY 1994 budget for immunization service delivery, more than doubling federal support for state and local health department immunization programs.** The increased appropriation will rebuild the public health infrastructure to eliminate long lines and waiting times that make it more difficult for families to get services. The new investment will help educate and provide outreach to parents about immunization services. The funds will also enable immunization programs to coordinate with programs like WIC and Medicaid that serve many families with young children who need immunizations.

CONCLUSION

The President has shown his leadership and vision on this critical issue. Congress must accept the challenge issued by the President and think boldly about the solutions needed to immunize every American child. If we do not seize this opportunity, it will take another cycle of falling immunization rates and resurgent childhood diseases to regain the momentum we have today. The Comprehensive Child Immunization Act of 1993 (H.R. 1640 and S. 732/733) is good for children and their families. It lightens the load for public health and strengthens the role of pediatricians and family physicians in children's health care. And, it provides assurances to the vaccine manufacturers of fair and reasonable prices and profits for their products. Please include the Comprehensive Child Immunization Act of 1993 in the Committee's budget reconciliation package.

PREPARED STATEMENT OF JEAN-PIERRE GARNIER

Mr. Chairmen and Members of the Committee and Subcommittee: My name is Jean-Pierre Garnier, Executive Vice President of SmithKline Beecham Pharmaceuticals.

SmithKline Beecham is a transnational health care company whose principle activities are the discovery, development, manufacture and marketing of pharmaceuticals, vaccines and other health care goods and services.

As far as vaccines are concerned, we are a major supplier of polio and measles vaccines outside the United States, and we market Engerix-B, a biotechnology-derived Hepatitis B vaccine in the U.S. and around the world. Every second of every day, fifteen people around the world are inoculated with one of our vaccines. We consider our R&D effort in vaccines second to none. We are working on Lyme Disease, Aids, and we recently introduced the world's first hepatitis A vaccine in Europe, and we presently plan to offer a full range of pediatric vaccines in this country.

SmithKline Beecham is in a partnership with the State of Michigan Department of Public Health. We plan to market Michigan's human rabies and DTP vaccines, and we are working with Michigan on the development of new combination vaccines for the future.

I am pleased to appear before you today as you consider an issue of great importance—the immunization of our children by the age of two. I will identify the approaches we favor, and comment on those which we believe need modification.

Few tasks are more important than the one before us, because nothing speaks more for any nation than how well it protects its children. America's record is not what it can and must be. We have much to do if we are to look back with pride at the end of this decade to a nation whose children are protected as well as any in the world against communicable illnesses.

There is no question that we can get the job done. We have a world class vaccine industry, dedicated health professionals, sophisticated distribution networks and the economic capacity to do it.

SmithKline Beecham applauds the objectives of the universal immunization proposal, and we favor many aspects of the Administration's proposal, particularly the following:

- Establishment of an immunization tracking system.
- Enhancing education and outreach programs.
- Securing the National Vaccine Injury Compensation Program by making it permanent.
- Continuing vaccine infrastructure enhancements.

While we support these important points, there are other areas where we believe modifications are in order. Universal government purchase creates several concerns:

- First, it would eliminate the private market, which can work quite well in ensuring immunization of children, particularly under managed care. One need only look at the Kaiser Permanente program in California, where childhood immunization is at 95%.
- Second, universal procurement coupled to winner-take-all bidding would erect an insurmountable barrier to entry for new players such as SmithKline Beecham. It is important to understand that because vaccine production cannot be shut down for months or years and restarted on the next bid, the losers under a winner-take-all approach would have to leave the business.
- Third, a system that could give a monopoly to one supplier could lead to a shortage of essential vaccines if that supplier were to experience production or quality control problems. Precisely this has happened in the recent past.
- Fourth, elimination of the private market would increase government outlays for vaccines, because prices to the public sector, which are now in effect subsidized by the higher prices derived from the private sector, will increase.

The current proposal also fails to address the inadequate compensation of physicians who are expected to immunize Medicaid beneficiaries. This has resulted in some patients being shifted from private physicians' offices to public clinics. As a consequence, many children are not being immunized. The March 1993 GAO report notes that, "even when states have established vaccine replacement programs, not all physicians have participated, because of what they perceive as inadequate reimbursement for vaccine administration."

And finally, the proposal should be changed to include an important role that should be performed by the private insurance market. Insurance companies should be required to contribute to the solution by covering the immunization of children they already insure.

While we do not endorse every facet of the Administration's proposal, we do not favor the status quo. Now, instead of turning the industry on its head by essentially creating a public utility concept, with a promise to turn us back on our feet with implementation of managed competition, we feel we have a better approach.

Let me summarize SmithKline Beecham's recommendations on how each of these issues may be addressed:

1. We advocate that CDC prices, currently the lowest prices in the market place, be made available to all state Medicaid programs.
2. We recommend that the CDC winner-take-all system be replaced by an apportioned bidding system, allocating a share of the bid to all bidders that meet the lowest price.
3. We support expanded (not universal) purchase to provide Medicaid immunization coverage to all children whose family incomes are 185 per cent of poverty. We also support coverage of the physician's fees to ensure needed follow-up visits to complete immunizations.
4. We recommend that private insurance be required to cover all American Academy of Pediatrics recommended childhood immunizations and that preventive care services, including immunizations, be made part of the basic health care benefit.

Our proposal achieves the results the Administration seeks, but at a much lower cost. If the Federal government were to purchase vaccines for all children and if a 95% immunization rate were reached, we estimate that the cost would be around $700 million annually. Under our proposal, the vaccine cost would be $240 million, a saving of $460 million. The savings could be applied to the public education effort, the infrastructure and tracking programs, and to Medicaid expansion.

Contrary to the universal purchase, our proposal preserves multiple vaccine developers and manufacturers, therefore avoiding potential serious disruptions of supply. Our proposal also focuses on the root causes of low vaccination rates at a substantially lower price tag for the taxpayers.

Our proposal represents a workable plan for achieving full immunization of our children, while avoiding the pitfalls of universal purchase and the severe inadequacies of the current system.

PREPARED STATEMENT OF SAMUEL L. KATZ

My name is Samuel L. Katz, M.D. and I address you today as an individual who has spent more than 36 years of his professional life devoted to research and development of childhood vaccines and to policy deliberations in their use, and ten years

as Chairman of the Advisory Committee on Immunization Practices of the U.S. Public Health Service. The prevention of infectious diseases by vaccines has been one of the great triumphs of modern preventive medicine. In 1992 the reported cases of vaccine-preventable diseases were reduced by greater than 97% to 99% from those numbers that occurred in years of peak incidence. These records of achievement have been eroded, however, on a number of occasions because access to health care is restricted for some deprived populations and this has resulted in outbreaks such as our experience with the recrudescence of measles from 1989 to 1991. Because the great majority of the children who acquired measles, suffered its complications, required hospitalization and died in those years were unvaccinated, they exemplify our failure to provide preventive health measures that reach every infant and child.

The provision of free vaccines to all infants and children in this country would be an admirable statement to demonstrate our nation's commitment to their health and well being. We endorse it with enthusiasm and full support. However, it is an oversimplification to believe that this measure alone would solve our problems.

For example, in at least eleven states vaccines are already provided free (Massachusetts, Connecticut, bode Island, New Hampshire, Michigan, South Dakota, Vermont, Washington, Wyoming, Alaska, and Idaho). Despite this, their records of children receiving the recommended vaccines by age two years, averages at best 63%. Data that became available in December 1992 from the National Center for Health Statistics Survey showed national figures of only 37%–56% up-to-date by age two years. Whatever the exact numbers may be, nowhere in this country do they approach the achievement for which we rightfully should aim—as close as possible to 100% by age 18 months! Free vaccines are of no use if they sit in the refrigerators of physicians' offices or health clinics. A vaccine distribution program must include the commitment to be certain the vaccines reach the children. Admittedly the solutions to this problem of vaccine delivery are multiple and not simple, but I am optimistic that the child advocacy goals expressed by our current administration can be implemented by a number of actions that will enable us to succeed.

Children and their parents must be provided ready access to vaccines. This can be in physician's offices, at clinics and in public health facilities. Additionally, however, imaginative approaches can be utilized to bring vaccines to those places where infants may gather—day care centers, churches, preschool programs, offices where their parents register for entitlement programs (WIC, Aid for Dependent Children, Medicaid, etc.), neighborhood shopping centers. In other settings outreach programs can be developed with mobile vans and other transport vehicles to go to playgrounds, housing developments and other places where parents with their infants may congregate. A related aspect is the hours at which immunization services are available. For single parents or for parents who both work, daytime hours are frequently impossible or so inconvenient that they are unrealistic. Nighttime and weekend access should be provided. Emergency rooms where children are brought for episodic care should automatically investigate a young patient's immunization status and provide vaccines on the spot when appropriate. The provision of a national registry from which a care provider could readily determine by computer linkage the immunization status of any child at the moment of contact would greatly ease the complexities and failures of current record-keeping strategies. Our public health infrastructure has been eroded these past 12 years, while additional burdens have been foisted on it (AIDS, environmental pollution, lead screening, child abuse etc.).

On another level, preventive medical measures should be a required inclusion in every health insurance or health care program that is offered. It is economically wasteful as well as morally unconscionable that many plans offer thousands of dollars of reimbursement for hospital care and complex technologic procedures, but fail to provide a few dollars for preventive measures such as vaccines. Whenever anyone wants to highlight a cost-effective medical measure, immunization is always selected because repeatedly it has been demonstrated that the cost-benefit analysis in dollars is highly favorable. More culturally-appropriate and imaginative educational programs must be mounted to educate and to attract parents to the vaccine programs for their children, in many instances to protect them against diseases (such as paralytic polio, whooping cough, diphtheria and measles) that young parents may never have seen. In this respect, our very successes have inadvertently and paradoxically become deterrents and led to complacency or even ignorance. The creativity of our media industry could be exploited to prepare attractive, enticing pro-vaccine presentations.

Two other issues, of significance merit attention if we are to succeed. The plethora of litigation, the great majority of which is totally inappropriate and frivolous, has been a deterrent to investment in vaccine research and development. In the mid 1980's we faced a national crisis when only two companies were producing required

childhood vaccines, and when one encountered production difficulties, a shortage arose. It was necessary at that time to arrange a rationing priority system. In 1993, in great part because of the effectiveness of the National Vaccine Injury Compensation Program that was enacted by Congress in 1986 and funded in 1988, we have experienced the enormous benefits of a major expansion of private investments in vaccine research and development. Instead of two national companies we now have four major manufacturers plus several foreign concerns that are entering the American market. In addition to these major producers and distributors, we have a multiplicity of biotechnology firms that are conducting innovative vaccine research facilitated by the molecular biology and immunology of the past decade. The National Vaccine Injury Compensation Program was allowed to lapse at the end of 1992 because of several complicated legislative maneuvers including presidential veto on 4 November 1992 of the Urban Renewal Act. As of 1 January 1993, the Secretary of the Treasury announced the termination of the excise tax that was prospectively funding this highly successful program. There must be prompt legislative action to re-install this program.

The development of any program for universal governmental purchase of all vaccines must carry carefully planned provisions that will encourage the continued participation of the new and existent companies that are currently engaged in vaccine research, development and production. Due to their major investments, we have exciting new vaccines already available that have, for example, nearly eliminated in the past 2 years haemophilus influenzae b the most common cause of childhood meningitis. At least three companies have been involved in the research that has brought these vaccines to market and they continue to provide new improvements. Our vaccine programs will be even more convenient in the coming months and years as multiple vaccines are combined into single products reducing significantly the numbers of injections and thereby the numbers of visits or contacts that an infant must have to obtain full protection. Although much of the funding for basic biomedical vaccine research stems from federal sources such as the National Institutes of Health, and the National Science Foundation, an additional infusion of hundreds of millions of dollars has come from the private companies who have funded the development and production aspects as well as the major clinical trials needed to demonstrate vaccine safety and efficacy in the field. A careful strategy must be devised to encourage the continuation of their investments whilst ensuring availability of vaccines at reasonable prices in order to provide them free to all children.

I have no doubt that our goals are identical and achievable. It is the strategies that we employ to achieve these goals that must be devised with judicious attention to the history of vaccine research and development, our successes as well as our failures, and the major problem in bringing together the available vaccines and the children who need them. Although our focus now is on the urgent need to protect infants and children from vaccine-preventable infectious diseases, we must not neglect the equally important requirement that these same infants and children have all the health services required to ensure their optimal growth, development and maturation. Thank you very much for this opportunity to contribute to the discussion.

PREPARED STATEMENT OF SENATOR EDWARD M. KENNEDY

I'm grateful to Chairman Riegle for inviting me to be here today. It is a privilege to participate in this hearing on a critical component of our nation's immunization policy—the affordability and availability of immunizations to all children. There is no simpler, more important, or more cost-effective investment in health care than childhood vaccinations. Yet half the nation's youngest children are poorly protected against preventable diseases.

The high cost of vaccines is part of the problem. So are other barriers that impose unreasonable obstacles to immunization. We can reduce or eliminate most of the barriers by better public outreach and education, by an immunization registry system, and by more effective public health clinics. The Labor Committee will soon mark-up a comprehensive proposal that addresses these problems, and we look forward to working with the Finance Committee to blend our two bills into a comprehensive plan.

You might even say, Mr. Chairman, that you are dealing with the supply side, we are dealing with the demand side, and we both are on the children's side.

The major issue under consideration today is the high cost of vaccine for many families, which discourages parents from obtaining timely immunizations for their young children. A second issue is reasonable reimbursement for providers who serve low income children.

Our neglect of these issues has led to an increasingly heavy burden on the public sector, as more and more parents are priced out of their family doctor's office for immunizations.

Data from the Current Population Survey shows that 71% of uninsured children are below 200% of the poverty level. Their families cannot afford $232 for early childhood vaccines, especially if there are several children in that family.

Not all insurance covers immunization. This gap will be closed by health care reform, but until that time, over three million children under two have no insurance for immunization. It is a national disgrace that any child should be turned away from a lifesaving and cost-effective immunization because of an inability to pay.

President Clinton has shown impressive leadership with his far-reaching proposal.

Our bipartisan goal is clear: universal access to immunization for all children, and I look forward to working with the members of the Finance Committee to make it happen as soon as possible.

PREPARED STATEMENT OF SENATOR DAVID PRYOR

Mr. Chairman. I thank you for calling this hearing and for your very important leadership in this Committee on the important issue of childhood vaccinations. Today, we are considering legislation to assure that more of our nation's children are vaccinated against terrible illnesses such as measles, mumps, and rubella. These illnesses can result in long-term inability to live life to its fullest. They also put an extra strain on our health care system in treating expensive medical conditions that could have been prevented.

It is clear to me that everyone can benefit from increasing the immunization rate for children. Children obviously benefit because they are protected from these diseases. The health care system benefits from reduced costs. Drug manufacturers benefit from increased sales of their vaccines in the United States, the largest market for vaccines in the world.

There appears to be lack of consensus, however, on how we achieve this goal of increasing immunization rates. The Administration has proposed what is being called a "universal purchase" program. It seems that the term "universal purchase" has set off alarm bells among the pharmaceutical manufacturers. From my reading of the bill, however, it appears that the program is more a "universal negotiation" rather than a "universal purchase," with appropriate safeguards to reward manufacturers for their research.

However, the manufacturers have rolled out their standard and all well-known arguments against the legislation. They have told us that this bill would result in the "nationalization" of the vaccine industry, and that vaccine research would become a fading memory.

There is no reason, however, that manufacturers should not negotiate over vaccine prices with the federal and state governments. Drug manufacturers negotiate with almost every industrialized nation in the world over pharmaceutical and vaccine prices. Why does the United States and its American citizens—which provide billions of dollars in taxpayer support each year to the pharmaceutical industry—constantly get the cold shoulder?

To add insult to injury, some states that have tried to buy vaccines for their populations at the Center for Disease Control's negotiated vaccine prices have been refused by the manufacturers. What good is a CDC price if it has limited availability?

Manufacturers' refusing to negotiate with some states over vaccine prices brings back memories of the state Medicaid prescription drug programs. Up until 1990, state Medicaid programs, seeking to negotiate with drug manufacturers over their prices, were consistently rebuffed by drug companies. This intolerable situation lead to the enactment of the Medicaid rebate law of 1990. So, it appears that this vaccine legislation is partially a result of the manufacturers' refusal—once again—to deal in good faith with some states.

While we certainly need to improve the vaccine delivery infrastructure, the impact of escalating costs on immunization rates cannot and should not be minimized. According to the Department of Health and Human Services, a MMR shot that cost $10.44 in 1982, cost $25.29 in 1992. That's an increase of 142 percent over that 10 year period. Remarkably, drug price inflation during that period was about 142 percent as well, while the general inflation rate was only 46 percent. The DPT shot increased from 37 cents in 1982 to $10.04 in 1992, an increase of 2,613 percent.

Poor and middle class families—of which there are many in Arkansas and all across the nation—do not have insurance that covers any type of health care service, no less vaccinations for children. The price of vaccines have become prohibitive for the average American family. Whether or not the escalating costs are due to new

vaccines, excise taxes, or price increases, they are still unaffordable. As our President said, these price increases are staggering, and are impeding the ability of our health care system to care for its children.

Mr. Chairman, to solve this urgent crisis in our American health care system, I think that everyone is willing to make concessions to do what is right for our nation's children. Over the past few days, the Administration, working with members of Congress, appear to be reaching a consensus on a compromise proposal that will increase the vaccination rate among poor and uninsured children.

Unfortunately, we are hearing that manufacturers may have concerns with that solution also. Vaccine manufacturers have been part of the problem, and now they have to be part of the solution. They have to be willing to do more about lowering their prices through honest negotiations. Negotiating is the American way, and will be the hallmark of managed competition. The manufacturers say that "managed competition" will contain drug prices in a reformed health care system. Their current actions relating to vaccines are not giving me much confidence that this will be the case.

Once again, I thank the chairman for calling this hearing. I hope to contribute to enacting legislation this year that will make the United States a world leader in childhood immunization rates.

[Submitted by Senator Donald W. Riegle, Jr.]

STATEMENT OF SUPPORT FOR THE COMPREHENSIVE CHILD IMMUNIZATION ACT OF 1993

We, the undersigned organizations, applaud President Clinton's initiative to protect all of America's children against preventable diseases. It is unacceptable that almost half of our nation's preschoolers are not fully immunized. The nation's shameful immunization record is a testament to the need for comprehensive health care reform to guarantee comprehensive health care coverage for all Americans. This legislation is an important step towards that goal.

The President's initiative will guarantee that no child will go unimmunized because his or her family cannot afford the shot. It is unacceptable that forty percent of American preschoolers are not fully immunized when each dollar invested in immunizations saves our society more than $10 in health care costs by preventing disease and disability. This legislation will also create a national immunization registry to follow the vaccination status of individual children. The registry will provide reminder notices to families for their children's shots and identify communities with low coverage rates for outreach and public education. The Act will also improve Medicaid coverage of immunizations for low-income children, and reauthorize the National Vaccine Injury Compensation Program.

Advocates for Children and Youth
American Academy of Family Physicians
American Association of University Affiliated Programs for Persons with Developmental Disabilities
American College of Nurse-Midwives
American Dental Association
American Federation of State, County, and Municipal Employees
American Federation of Teachers
American Hospital Association
American Indian Health Care Association
American Public Health Association
American School Health Association
American Speech-Language-Hearing Association
The ARC (formerly the Association of Retarded Citizens)
Association for Supervision and Curriculum Development (ASCD)
Association for the Care of Children's Health
Association of Junior Leagues International
Association of Maternal and Child Health Programs
Association of Schools of Public Health (ASPH)
Association of State and Territorial Health Officers
Bridgeport Child Advocacy Coalition
Catholic Charities, USA
Child Welfare League of America
Children Now
Children's Advocacy Institute (California)

The Children's Council of San Francisco
Children's Defense Fund
The Children's Foundation
Children's Health Fund
Children's Policy Institute of West Virginia
Citizens for Missouri's Children
Colorado Children's Campaign
Consumers Union
Florida Children's Forum
Friends Committee on National Legislation
Georgia Alliance for Children
Hadassah, the Women's Zionist Organization of America
Human Development Center of Mississippi
Interfaith Impact for Justice and Peace
Infectious Diseases Society of America
Jesuit Social Ministries, National Office
Lutheran Office of Governmental Affairs (ELCA)
March of Dimes Birth Defects Foundation
Massachusetts Advocacy Center
Massachusetts Committee for Children and Youth
Michigan Head Start Child Development Association
Michigan League for Human Services
Mississippi Human Services, Agenda
National Association for the Education of Young Children
National Association of Children's Hospitals and Related Institutions
National Association of Community Action Agencies
National Association of Community Health Centers
National Association of Developmental Disabilities Councils
National Association of Partners in Education, Inc. (NAPE)
National Association of WIC Directors
National Black Child Development Institute, Inc.
National Black Nurses Association
National Community Education Association (NCEA)
National Easter Seal Society
National Indian Education Association
National PTA
National Parent Network on Disabilities
New Hampshire Alliance for Children and Youth
Office of Domestic Social Development, U.S. Catholic Conference
Pennsylvania Partnerships for Children
Philadelphia Citizens for Children and Youth
Planned Parenthood Federation of America
Results, Inc.
San Francisco Child Abuse Council
Service Employees International Union
Statewide Youth Advocacy, Inc.
Sudden Infant Death Syndrome Alliance (SIDS Alliance)
Unitarian Universalist Association of Congregations
United Auto Workers of America
United Cerebral Palsy Associations
The Vaccine Project
Vermont Children's Forum
Virginia Perinatal Association
Wisconsin Council on Children and Families, Inc.
Women's Legal Defense Fund
Zero to Three/National Center for Clinical Infant Programs

United Pediatric Society
721 East Huron • Ann Arbor, MI 48104
(313) 996-4496 • FAX (313) 996-0455

May 4, 1993

Senator Donald Riegle
105 Dirksen Office Building
Washington, D.C. 20510

Senator Edward Kennedy
United States Senate
Washington, D.C. 20510

Dear Senators:

The United Pediatric Society represents 150 Pediatricians in Michigan. While we agree with you in principle that all children should be immunized before age two when they are the most vulnerable, we have serious concerns about some parts of S.732 and S.733, the Comprehensive Child Immunization Act.

Our experience in Michigan, where most vaccines are available through the Public Health Department, tells us that the fragmentation of receiving health care in one location, and immunization in another, leads to the under-immunization of those most at risk. Your bill seems to perpetuate this schism in health care and immunization. The bill creates a very frustrating reporting system for the private practitioner which will foreclose their participation in the immunization program, and further erode access to vaccines. We encourage you to look to new solutions that require input and assistance from the private practitioner in designing user friendly tracking and outreach which will put these federal dollars to work in the most cost-effective way.

Since the burden of reporting in a tracking system falls on the individual Pediatrician's office, we are concerned about how the tracking system will be set up. Some pediatricians' offices do not have computers. As we read the language in the bill, it would appear to require much additional paperwork or telephone time by our office staff. We need less, not more record-keeping in our professional lives. We encourage the adoption of a standard claim form (HCFA1500) as a reporting device. This would not require additional paperwork or education.

The private sector physician needs to be clear on what is expected if they accept the government purchased vaccine. As the bill now reads, we may charge an administration fee for the immunization, but if the parent refuses or cannot pay, we must still give the vaccine. This is not an encouragement for a pediatric practitioner to be involved in the system. Also, it certainly does not recognize the realities of medical office costs. Again, another indication that this bill is not physician friendly.

We wish to point out that kids can get their shots in a Public Health facility, but they must get their health care from a physician. If we do not make an effective change from the system as it now stands, there will be no improvement in the health status of these kids. Their care will not be managed, it will be fragmented. They will be immunized in different places and will be treated in the Emergency Rooms. The most difficult and highest risk case is one that walks in to an E.R. off the street. If private practitioners could be

involved by making a simple, fair system to report and pay for vaccines, the child's health care supervision would be assured as part of the vaccine program. We are hopeful that President Clinton's Health Reform will address the universal coverage that will pay for these children in a physician's office. In the interim, please do not close out private sector participation in your immunization legislation. It is a good start on a solution to present child health care problems.

Sincerely,

Jude Huetteman

Jude Huetteman
Executive Director

cc: Debbie Chang
Deborah Vaughn-Zinkernagel

PREPARED STATEMENT OF RONALD J. SALDARINI

Lederle-Praxis Biologicals welcomes the involvement of the Finance Committee and this Subcommittee in the debate over how to improve childhood immunization in this country, and we appreciate the opportunity to participate. While the proposals of the Administration appear to be in flux, it is certainly possible to conclude that none of the various approaches being considered will improve immunization rates in this country and to identify elements of those proposals which remain problematic to vaccine manufacturers.

In a recent report to the Chairman of the full Committee, the General Accounting Office found that "[t]o improve immunization levels, state and local immunization programs need to (1) educate parents on the importance of immunizations for their children, (2) track each child's immunization status, and (3) follow up with children needing immunizations."[1] Within this Committee's jurisdiction are the primary keys to achieving these goals—Medicaid and private insurance. Until those critical components are harnessed to the benefit of improved immunization, all of the Administration's proposals are doomed to failure—and expensive failures at that. The focus of both the Finance Committee and of industry should be on means to improve immunization results for the vulnerable Medicaid population and those with private insurance that does not cover immunizations and other well-child services.

THE MEDICAID POPULATION AND FAILURES OF EPSDT

Medicaid provides health care coverage for somewhere between one-third and one-half of our nation's children. Most experts believe that the problem of low immunization rates is most acute in the Medicaid population. In the current discussion regarding the Administration's proposal for universal purchase of childhood vaccines by the federal government, a commonly stated rationale is the need to encourage a "pediatric home" for children with private insurance. Lost in this discussion is the corresponding, if not greater, need for a primary care pediatric home for Medicaid children. Whether provided in the context of Medicaid managed care as proposed last year in legislation sponsored by Senator Moynihan[2] or through some other mechanism, there is a clear need for a more organized approach to primary care in the Medicaid population, particularly in connection with well-child care, including immunizations. Mere access to free vaccines by Medicaid programs will not ensure that the vaccines reach children at risk.

Since 1967, the Medicaid statute has included a program known as Early and Periodic Screening, Diagnosis and Treatment (EPSDT). This program, which is mandatory for Medicaid plans, provides for screening and outreach as well as immunization services. Medicaid recipients are entitled to these services, but in fact they are not available in many locations. In order to stimulate the states into enforce-

[1] GAO/HRD–93–41, Report to the Chairman, Committee on Finance, U.S. Senate, "Childhood Immunization: Opportunities to Improve Immunization Rates at Lower Cost," (March 1993).
[2] *See* S. 2077, 2d Sess. 102d Cong. (1991).

ment of EPSDT requirements, Congress in 1989 established new incentives and additional guidelines for implementation of the program.[3] However, at present, EPSDT continues to be largely a failure in providing Medicaid children with the immunization services to which they are entitled by statute.

This Subcommittee recognized the pivotal role of EPSDT in a hearing held less than a year ago in which a variety of witnesses—many of them visible participants in the current immunization debate—spoke of the inadequacies of Medicaid in providing immunizations as well as any other health care to children.[4] The principal reason given for low compliance with EPSDT requirements was unrealistic reimbursement levels for physicians and the resulting physician refusal to participate in Medicaid in a meaningful fashion. The Committee also identified a number of other factors, including limited and uncoordinated outreach to Medicaid children and poor state and federal leadership in implementing and monitoring EPSDT. To date, these deficiencies remain largely uncorrected.

A PEDIATRIC HOME FOR PRIVATELY INSURED CHILDREN

The need for a pediatric home is not limited to Medicaid children but is also applicable to those with health insurance that fails to cover immunizations and other well-child care. At last month's hearing on the Administration's proposal, Dr. Sienko, a Michigan public health official, stated that 370 of the children coming to his clinic for immunizations were enrolled in private insurance plans.[5] This statistic underscores the inadequacy of private health insurance as it currently applies to well-child care, including immunizations.

One proposal apparently under consideration by the Administration would target free vaccines not only to Medicaid children but also to "the uninsured," possibly including those with insurance but no specific coverage for immunizations. The provision of free vaccine to children with adequate means will undermine the momentum of efforts to provide comprehensive well-child coverage, including immunizations. A better approach would be for the Finance Committee to take steps to mandate first-dollar coverage of immunizations in all health insurance policies.

Just this week, the *Washington Post* editorialized against the cornerstone of the Administration's original proposal, universal purchase of all childhood vaccines. Presumably, the *Post* editorialist would also conclude that the de facto universal purchase being offered as a compromise is not "the best use of scarce dollars for public health." Possibly more significant, however, than the potential waste of limited funds is the lost opportunity to address well-child care in a comprehensive fashion:

> "You have to wonder why the Administration has floated this particular legislation, without a means to pay for it, before the broader proposals for reform that will surely affect vaccine cost, delivery and the nature of the public/private partnership that currently exists. Immunization, after all, is just a part of the care owed to a group—pregnant women and children—that this country is failing in large numbers."[6]

As the *Post* suggests, ill-conceived piecemeal approaches will be nothing but counterproductive.

WHAT THE FEDERAL GOVERNMENT CAN DO TO HELP

There are a variety of short- and longer-term measures which could be taken by the federal government to improve the critical shortcomings in both Medicaid and private insurance coverage of immunizations. The short-term steps which the government should take include:

- Target limited resources on improving delivery of vaccines throughout the public health system, including development of a user-friendly tracking system, increased funding for expansion of clinic hours and other measures to make immunization more convenient for Medicaid recipients, and aggressive outreach to immunize hard-to-access children.
- Provide new guidance from the Health Care Financing Administration to state Medicaid programs concerning immunization standards which incorporate new vaccines and new schedules.

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[3] 1989 Omnibus Budget Reconciliation Act, PL. 101–239.

[4] Hearing before the Senate Finance Subcommittee on Health for Families and the Uninsured, "Impact of Medicaid on Child Immunization," June 1, 1992.

[5] Testimony of Dr. Dean Sienko, Medical Director of Ingham County Health Department, Lansing, Michigan, at a Joint Hearing of the House Energy and Commerce and Senate Committee on Labor and Human Resources, April 21, 1993.

[6] Washington Post, May 3, 1993 at A16.

- Increase Medicaid physician reimbursement with respect to immunizations.
- Eliminate barriers to participation of states in Medicaid replacement programs to ensure that Medicaid recipients obtain discounted vaccines.

Longer-term, the federal government should fully implement EPSDT requirements to give this program a chance to work. The statute contains ample direction to the states regarding the rights of Medicaid children to screening, immunization and other preventive health care services. What is now needed are the resources and the will to make those rights real.

PRICING POLICIES OF VACCINE MANUFACTURERS

Like the federal government, vaccine manufacturers are often confronted with competing demands. Throughout the past decade, manufacturers have been faced with pleas from parents, pediatricians and public health officials to develop new vaccine products. The price increases which have been a target for criticism were necessary, in substantial part, in order to fund the research and development that has resulted in important new pediatric vaccines and created the realistic hope of other new products in the not-too-distant future.

One of the criticisms erroneously leveled at manufacturers has been the assertion that the prices of American-made vaccines are higher in this country than abroad. Since my company is the largest American manufacturer, indeed one of only two American-owned companies remaining in the market, we are particularly qualified to respond to that assertion. For the moment, we are selling only one product in other countries, our conjugate vaccine for haemophilus influenzae type b (Hib). In the 15 international markets where that vaccine is sold, the overall average price is 47% higher than the average U.S. price. Where the vaccine is sold in the private sector, the price is 15 higher than the U.S. private price. In markets where there is a public purchase, the average international price is 79% higher than the U.S. price to the public sector.

We find it ironic that the price of our Hib vaccine is readily accepted in underdeveloped countries while prices in the United States for the same product are subject to substantial criticism. The foreign countries purchasing this vaccine do so because they are willing to pay for a quality product, particularly when it is one which is demonstrably cost-effective. Everyone praises the cost-effectiveness of childhood vaccines, but if we ultimately are unwilling to pay a fair price for them, that appreciation is meaningless.

WHAT INDUSTRY CAN DO TO HELP

We believe that there has been a satisfactory partnership between vaccine manufacturers and the public sector, both federal and state, over the past decade, which has seen many threats to the childhood immunization program but also many successes. We recognize that industry, like government, must do its part to enhance the immunization effort.

Short-term, industry is prepared to do the following:

- Continue to provide vaccine to the public sector at substantially discounted prices.
- Work with government to ensure that more Medicaid and truly needy children without health insurance have access to public sector vaccines, and that government's limited resources are targeted to immunization of those children.
- Provide education and technical assistance to both the public sector and private pediatricians to fill gaps in the public health system.
- Follow a responsible policy on pricing (Lederle-Praxis, for example, has agreed to freeze prices for 1993 and to hold prices on individual products to the CPI for 1994).

For the longer term, Lederle-Praxis and the other vaccine manufacturers are committed to continuing their intense research and development efforts to find new antigens and to create new combination products. The success story of the Hib vaccines, having nearly eradicated a disease estimated to cost the United States $2.5 billion a year, demonstrates that such continued efforts are a good investment, not only for manufacturers but more importantly for the nation and its children.

QUESTIONS YET TO BE ANSWERED

Whether Congress considers outright universal purchase or a de facto version of the same concept, there remain a number of questions which need answers before these proposals should be adopted. Among them are the following:

What is the significance of the CDC data on low immunization rates? Dr. Moen from the Minnesota Department of Health testified at the April 21 hearing that the single number methodology employed by CDC was misleading in its failure to distinguish between children who have received no immunizations at all and those who have received 7 of 8 required shots, conferring effective immunity from disease in many cases.[7] In light of questions about the methodology, should we allocate farce resources based on gross immunization rates rather than targeting those resources to specific locations where immunization efforts are clearly deficient?

How cost—effective is universal purchase as an immunization strategy? To the extent that resources are limited, is universal purchase (or a variation thereof) the best use of limited funds in lieu of investment in delivery, tracking, education and other infrastructure improvements?

Are referrals from private pediatricians' offices to public clinics a substantial contributing factor to low immunization rates? Proponents of universal purchase refer to data reflecting increased referrals to public health clinics because of the cost of vaccines in private pediatric offices. However, the data do not indicate the extent to which significant numbers of children have been turned away from private offices (as opposed to the numbers of physicians who have turned children away), nor do the data indicate whether low reimbursement rates for Medicaid may play an important part in such actions by private physicians.

Has the Administration proposed a tracking system suitable for nationwide use? Even before the Administration's proposal has become law, states are objecting that the tracking requirements are burdensome and, in some cases, inconsistent with existing systems. If the federal government is to provide guidance to the states, it should do so through a process of consultation and not a prescriptive manner.

What incentives, both positive and negative, are appropriate for encouraging compliance with age-appropriate immunization schedules? The April 21 hearing revealed substantial divergence of opinion, to some extent even within the Administration, as to what incentives would improve immunization rates for children under age two. Obviously, the answer to this question has been solved with respect to school-age immunization, and a similar straightforward approach may prove equally effective in the case of younger children.

What existing programs to enhance immunization have worked in different states, and what elements of those successful programs should be translated to other states? Both the Centers for Disease Control and the media have identified the State of Georgia as having a model delivery, outreach, and education system. Georgia has accomplished marked improvements in immunization rates with no new funds. Should we be embarking on a major, costly new nationwide initiative without first examining what Georgia and other states are doing right?

What will be the impact on innovation in the vaccine industry if the government becomes sole or primary purchaser? The vaccine manufacturers have strongly asserted that research and development is threatened if the government controls the vaccine market. The Administration as strongly asserts the opposite conclusion. Few, however, are focusing on the fact that the Administration has contracted with a nationwide group of economists to study this very issue. Should the Administration not have waited for the experts to deliberate before proceeding with its universal purchase plan or any other major change in the government's purchase program?

What could be done further to improve EPSDT specifically and Medicaid for children generally, or to encourage private insurance plans to cover immunizations? As noted above, Medicaid currently has a mechanism for requiring comprehensive immunization services, but the requirements are not enforced. The Finance Committee has asserted jurisdiction over private insurance plans and could mandate coverage of immunization services. Would it not be better to enforce existing requirements or to employ the familiar device of an insurance mandate rather than undertaking a program which virtually nationalizes a successful and innovative industry?

Finally, and most importantly, why undertake these precipitate and massive changes in the immunization program without waiting for implementation of comprehensive health care reform? The Administration has rejected a single-payer approach as the answer to health care reform, relying instead on the marketplace. What is the rationale for rejecting the marketplace and embracing a single-payer approach with respect to one relatively minor segment of the health care industry, especially when that segment has been among the most responsible in terms of offering its products to the public sector at deeply discounted prices?

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[7] Testimony of Michael E. Moen, M.P.H., Director, Division of Disease Prevention and Control, Minnesota Department of Health, at the Joint Hearing, April 21, 1993.

Serious questions deserve serious consideration, which is not possible in a timeframe of weeks—all the time that we have before budget reconciliation is upon us. (The last-minute substitution of an alternative approach exacerbates the problem of inadequate time for careful consideration of options and their impact on immunization systems.) Vaccine manufacturers are willing to engage in discussions with public health experts, with Administration officials and with Members of Congress regarding ways to improve the childhood immunization program, but such discussions require time as well as good faith. We urge this Committee and the Congress to resist the Administration's insistence on fast-tracking its various universal purchase proposals so that these matters may receive the careful deliberation they deserve.

PREPARED STATEMENT OF HON. DONNA E. SHALALA

Thank you, Mr. Chairman. Let me start by saying that I'm especially pleased to testify before your subcommittee on the vitally important issue of immunizing our children against preventable infectious diseases.

As you know, this is my second visit to the Senate to discuss this issue and I am proud to reaffirm the Administration's commitment to immunizing children.

Today, I want to discuss the state of childhood immunizations in the United States, describe the actions taken thus far by this Administration to improve our Nation's immunization policies, and review the key provisions contained in the President's Comprehensive Child Immunization proposal.

The problem is enormous. Although 95 percent of school-age children are properly immunized, our pre-school vaccination rates are dismal. According to the centers for Disease Control and Prevention (CDC), some 40 to 60 percent of American toddlers have not received the proper vaccination series by their second birthday. In some inner-city areas, the vaccination rate is as low as 10 percent.

A brief look at this chart shows that to be fully immunized a child must be protected against nine diseases. Administering the entire sequence of shots is no easy matter. Full immunization requires that a child be inoculated 18 times with five vaccines, and all but 3 of the 18 doses should be received by age two. (This regimen would require 5 additional visits to the doctor's office in the first two years of life—at 2 months, 4 months, 6 months, 12 months and 15 months).

America's immunization delivery system is in shambles. Reductions in resources, increases in disease incidence, and patient shifting from private providers to public-sector clinics have out-stretched our abilities to identify children who need vaccinations and provide them. There are not enough clinics, and where they do exist, they are often understaffed, and closed during critical hours.

American families are getting squeezed by the sky rocketing prices of vaccines. As this accompanying graph illustrates, the vaccine cost to fully immunize a child has increased significantly from 1982 to 1992. In 1982, the cost of vaccine to fully immunize a child in the public and private sectors was approximately $7.00 and $23.00, respectively. By 1992, those costs had risen to $122.00 in the public sector and $244.00 in the private sector. In part, these increases can be attributed to recommendations for new vaccines, additional doses of existing vaccines, and an excise tax used to fund the vaccine compensation program.

But these factors do not account for the net increase in the cost of *existing* vaccines. For example, another graph I'd like to share with you shows that in 1982, the measles, mumps and rubella, or MMR vaccine, cost over $10.00 per dose in the private sector—but by 1992 the same dose cost over $25.00. Even if you subtract the $4.44 per dose excise tax instituted in 1988, the price of the MMR vaccine still doubled. The diphtheria, tetanus, and pertussis vaccine or DTP, increased even more sharply—from 37 cents in 1982 to a whopping $10.04 in 1992. With the $4.56 excise tax excluded, that's a net price increase of $5.11, or almost a 14-fold hike per dose.

What is the societal cost? According to the most recent estimates from the CDC, the failure to immunize our children on time led to the measles resurgence between 1989 and 1991. This epidemic resulted in over 55,000 cases of measles, 130 deaths, 11,000 hospitalizations, and 44,000 hospital days—with an estimated $150 million in direct medical costs. And that doesn't include the massive indirect costs stemming from lost time on the job, lost productivity, and lost wages, costs that could have been avoided by merely providing families with a vaccine that cost about $24.00 a dose in 1988.

I'd like you to look at another chart I have brought here today. It graphically illustrates that the United States has one of the lowest immunization rates for preschool children when compared with European countries. And note that for the United States, the percentages are for children aged 1 to 4, while the European fig-

ures are for children under 3 for DTP and Polio, and under 2 for measles. Parenthetically, I would also note that data from the World Health Organization places our immunization rates for one dose of measles vaccine by twenty-four months of age behind countries such as Argentina, Costa Rica, Grenada and even Cuba.

We cannot allow this situation to continue. We must ensure that our children are appropriately immunized against preventable infectious diseases. To accomplish this, we have proposed a coordinated action plan designed to remove the existing barriers to childhood immunization.

As you know, the President's jobs bill included an additional $300 million to strengthen this country's immunization infrastructure. These funds would have helped communities to immediately strengthen delivery systems, broaden outreach efforts, increase access to immunization services, enhance parent and provider education programs, and provide a host of other essential activities.

We continue to believe that these resources are desperately needed at the local level to improve vaccine delivery systems and immunization services. In response to that need, the President's fiscal year 1994 budget request for the immunization program at the CDC almost doubles, from $341 million in fiscal year 1993 to over $667 million in fiscal year 1994. With this renewed commitment, the CDC will be able to fund the State Immunization Action Plans for infrastructure development. The fiscal year 1994 request also would provide the States with the seed money to begin to develop a State-based vaccine and immunization registries.

I am pleased to announce today, that I have asked the Director of the CDC to create a National Immunization Program that will report directly to the CDC Director. The establishment of this high level organization within CDC to oversee our national efforts for childhood immunization is in keeping with the President's and my Department's initiative to ensure that all children in the United States are protected against vaccine-preventable infectious disease by their second birthday. This organizational change will increase the visibility, focus on the importance, and prepare for future improvements of the childhood immunization program.

However, these endeavors alone are not enough. We, the elected and appointed leaders of this Nation, must commit ourselves to ensure that all children are appropriately immunized by two years of age.

We know that the high price of vaccines is a significant financial barrier to obtaining vaccinations. We also know that the absence of immunization registries has impeded local and state efforts to ensure that all children are vaccinated on time. We must maintain a viable Vaccine Injury Compensation Program to increase public confidence in the safety of vaccination. And finally, information for parents on the benefits and risks of vaccines must be presented in clear, concise, and understandable terms.

Mr. Chairman, as an original cosponsor of the President's Comprehensive Child Immunization proposal, you well know the problems we are facing. We believe that proper immunization should be a basic right for every child in America—rich or poor—just like in most other industrialized countries.

As originally advanced, the proposal authorizes the purchase of all vaccines by the Federal government to be given at no cost to providers. Such a program would end the overburdening of our public health facilities by stopping patient shifting from private providers to public clinics, reinforce the essential link between the child and the family physician or pediatrician, and help build the Nation's vaccine manufacturing capacity by stimulating competition in a stable and assured market. But most importantly, we believe that providing vaccines universally to all children is the best means to achieve the desired end: the immunization of all children at the appropriate age.

The best example of how universal distribution makes a difference is the State of Washington. Washington began its universal system in September, 1990. The number of doses administered in Washington has climbed from 608,000 in 1990 to 835,000 in 1992. Almost all of the additional doses were administered by private physicians. As a result, the percentage of immunizations administered by private physicians has climbed from 57.7 percent in 1990 to 69.1 percent in 1992. This 40 percent increase in the number of vaccinations administered by private physicians proves that private providers will participate in a universal distribution program.

As we all know, despite the inherent advantages of universal purchase, considerable resistance to the Federal purchase of vaccines for all children continues. We believe that the immunization crisis requires that we move forward this year and establish a program for immunizing the greatest number of children. As a result, we have, in collaboration with the House Energy and Commerce Committee, refocused the universal access provision and reduced the cost of this portion of the initiative. And as you know, we are also discussing these modifications with the Senate Finance and Labor and Human Resources Committees.

Under the new provision, vaccines would be provided to States for free distribution to health care providers who serve children enrolled in Medicaid or who don't have health insurance that covers immunization services. Such providers would not be allowed to charge patients for the cost of vaccines, but could require a fee for vaccine administration. States could also choose to purchase vaccines at the CDC negotiated price for other segments of their population. By freeing up these resources, states could reinvest these funds in outreach and educational programs.

In addition, the provision would increase immunization levels of children receiving Medicaid by requiring States to reimburse providers reasonably for vaccine administration. Medicaid programs would require States to set immunization administration fees high enough, i.e., competitive enough to guarantee access to providers on par with the general population. States will be able to finance the increased reimbursement within the savings they will realize from our new vaccine purchase arrangement.

We cannot ensure that children are immunized unless their families and health care providers know which vaccinations they need and when they need them. That's why the President's proposal provides for a State-based immunization registries. The system would notify parents when immunizations are due and remind them if they do not keep appointments.

Providers would be required to report to the state registries data for each vaccine administered. The efficacy and safety of vaccines would be monitored by linking vaccine administration records with adverse events and disease patterns. The Administration proposal also would require that security measures be established to assure the confidentiality of the information collected.

Federal grants would be provided to states to establish and operate State- and local-based registries containing immunization histories, types and lot numbers of vaccines received, health care provider identification, demographic data, and notations of adverse events associated with immunizations.

State information systems would be coordinated at the national level by linking State systems and transferring immunization records when the child relocates to a new state.

A functioning National Vaccine Injury Compensation Program is critical to the national immunization effort. The very few children who suffer vaccine-related injuries must be compensated for those injuries, and so should their families.

We will also continue to seek reauthorization to make payments from the Vaccine Injury Compensation Trust fund and provide for the reinstatement and permanent extension of the vaccine excise tax, so that funding would continue to be reserved for the Compensation Program.

Finally, because there has been considerable misinformation about this proposal, I want to speak to what it does not do. It does not establish a federal requirement that all children be immunized against the wishes of their parents or guardians. It does not establish a Federal registry system that will force children to be immunized, nor one that will "track" children for some undefined motive.

Great nations invest in their people—and no investment is more fundamental and more cost effective than immunizations. We can and must develop a comprehensive program to reduce barriers to immunizations and to protect our children—the future of our country and our greatest natural resource.

Attachment.

ACIP Recommended Schedule of Vaccinations for All Children

Vaccine		2 Mos[1]	4 Mos	6 Mos	12 Mos	15 Mos	4-6 Years (Before School Entry)
DTP		DTP	DTP	DTP		DTaP(DTP)[2]	DTaP(DTP)
OPV		OPV	OPV			OPV[2]	OPV
MMR						MMR[3]	MMR[5]
HbCV							
Option 1[4]		HbCV	HbCV	HbCV		HbCV	
Option 2[4]		HbCV	HbCV		HbCV		

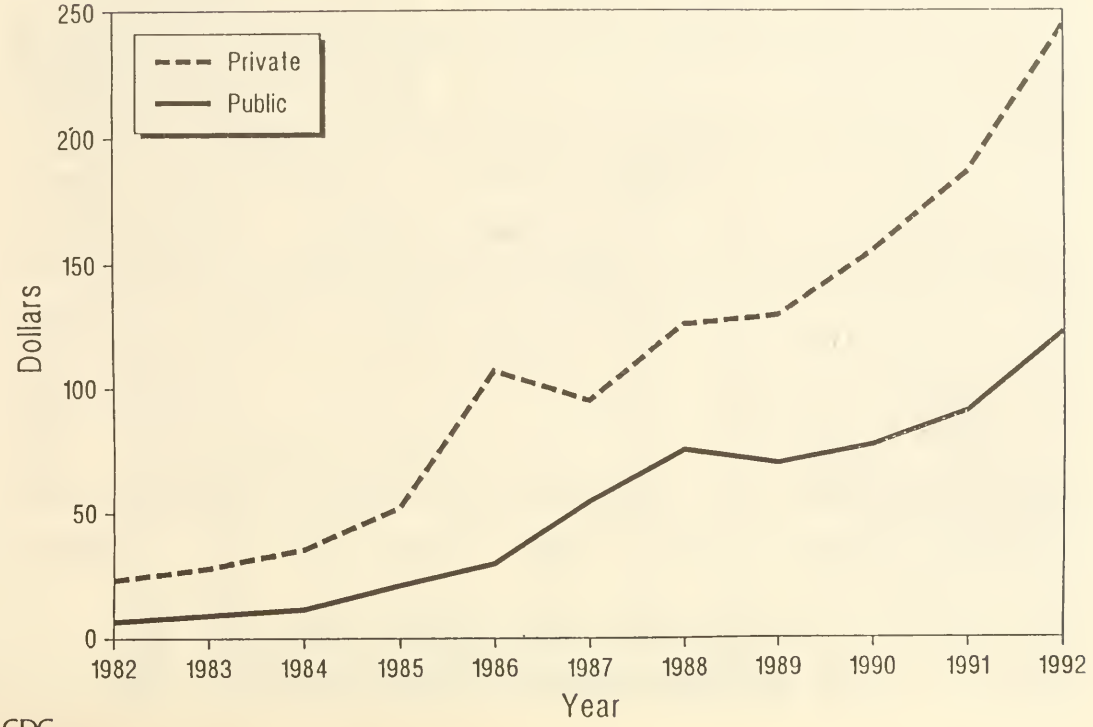
Vaccine	Birth	1-2 Mos	4 Mos	6-18 Mos	
Hep B[6]					
Option 1	Hep B	Hep B[7]		Hep B[7]	
Option 2		Hep B[7]	Hep B[7]	Hep B[7]	

DTP: Diphteria, Tetanus, and Pertussis Vaccine
DTaP: Diphteria, Tetanus and acellular Pertussis Vaccine
OPV: Live Oral Polio Vaccine
MMR: Measles, Mumps, and Rubella Vaccine
HbCV: *Haemophilus* b Conjugate Vaccine; consult package insert for recommendation for specific product used
HBV: Hepatitis B Vaccine

CDC

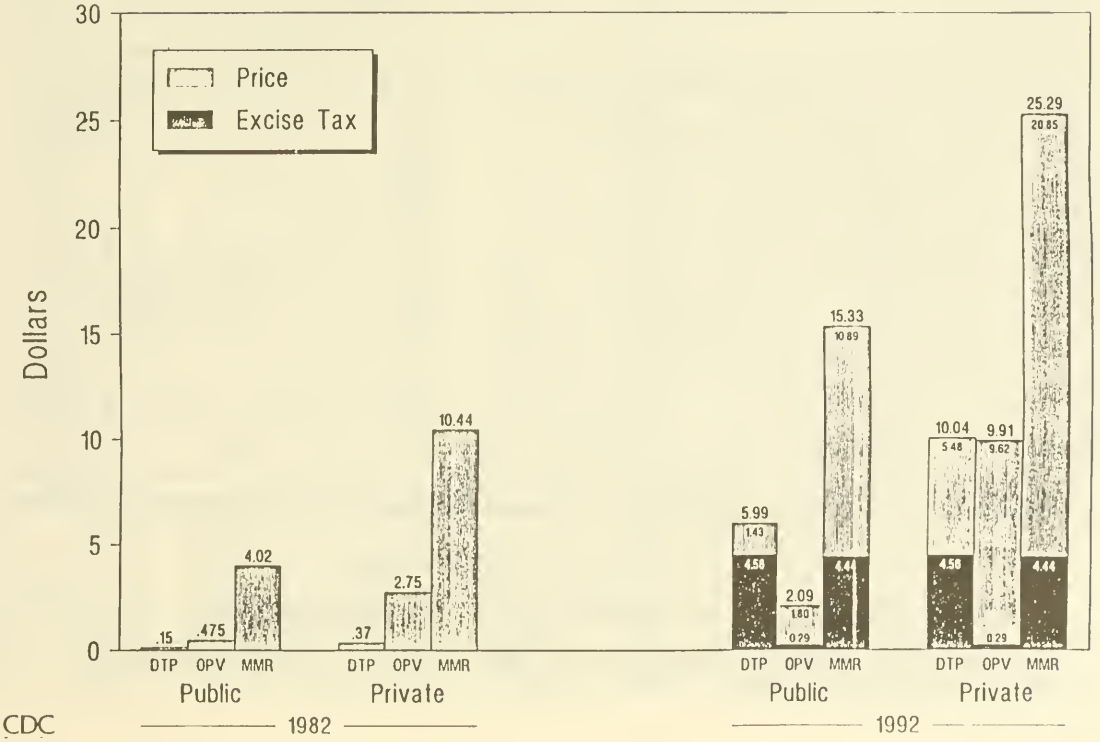
[1]Can begin at 6 weeks of age.
[2]Many experts recommend these vaccines at 18 months.
[3]In some areas this dose of MMR vaccine may be given at 12 months.
[4]HIB vaccine is given in either a 4-dose schedule (1) or a 3-dose schedule (2), depending on the type of vaccine used.
[5]American Academy of Pediatrics recommend this dose of MMR vaccine be given at entry to middle school or junior high.
[6]For infants born of HBsAg-negative mothers. (Infants weighing <2000 grams, Option 2 preferred, giving 1st dose at 2 mos).
[7]Hepatitis B vaccine can be given simultaneously with DTP, Polio, MMR, and *Haemophilus* b conjugate vaccine (HbCV) at the same visit

Vaccine Costs to Fully Immunize a Child 1982 Through 1992, Public and Private Sectors



CDC

Price Per Dose - 1982 Versus 1992
Public and Private Sectors



CDC

Immunization Rates for Preschool Children in the United States and European Countries

(Most Recent Available Year)

Figures are in percent

Country	Year	DTP[a]	Measles[b]	Polio[c]
Belgium (estimated)	1987	95.0	90.0	99.0
Denmark	1987	94.0[d]	82.0	100.0
England and Wales	1987	87.0[e]	76.0	87.0
France (estimated)	1986	97.0	55.0	97.0
Germany (FRG) (estimated)	1987	95.0	50.0	95.0
Netherlands	1987	96.9	92.8	96.9
Norway	1987	80.0	87.0	80.0
Spain	1986	88.0	83.0	80.0
Switzerland	1986	90-98	60-70	95-98
United States[f]	1985	64.9	60.8	55.3

[a] Three doses or more. U.S. rates are for children aged 1 to 4; European figures are for children under 3.

[b] U.S. rates are for children aged 1 to 4; European figures are for children under age 2.

[c] Three doses or more. U.S. rates are for children aged 1 to 4; European figures are for children aged 1 to 3.

[d] Rate is for combined diptheria, tetanus, and polio immunizations. Pertussis (89 percent coverage) and oral polio vaccines are given at separate visits; sequential immunization against polio by both injectable and oral vaccines is recommended.

[e] Rate is for diptheria and tetanus; rate for pertussis immunization is 73 percent.

[f] Immunization rate data for the United States are shown for the total sample population of the 1985 United States Immunization Survey, the last year the survey was taken

SOURCE: B. Williams and C. Miller, Preventive Health Care for Young Children Findings from a 10-County Study and Directions for United States Policy. 1991

PREPARED STATEMENT OF HEIDI SNARR

Mr. Chairman and members of the subcommittee, thank you for the opportunity to appear before you to speak on the issue of childhood immunizations. My name is Heidi Snarr and I am here to tell you about my struggles and frustrations in getting immunizations for my two children. I have a son, Matthew, who is three and a half years old, and a daughter, Beth Anne, who is 16 months.

My family, like many families with private health insurance, is not covered for immunizations and has been referred by our private physician to public clinics for our children's immunizations. We hear talk about the immunization crisis but the cost of vaccines has become an obstacle in getting our children properly immunized. I truly believe that preventive medicine is best administered by the child's primary care physician. Timely immunizations are an integral part of insuring a healthy period of growth and development for a child. It doesn't make sense that those of us who are already connected with a health care provider must go to an alternate source for immunizations simply because our income or insurance does not allow us to receive vaccines during our regularly scheduled check-ups. There ere many reasons why parents who leave their doctor's office without having vaccinated their children will not get to the public health department. If cost had not delayed their getting the service, each of these children would be fully immunized.

My family, which also includes my husband Alan, has been living in Lansing, Michigan for the last five years. Alan is a full-time doctoral student and teaching assistant at Michigan State University. This enables us to purchase health insurance for the family through a student health plan. My part-time teaching job at a local community college does not entitle me to health coverage.

We pay approximately $300 monthly for our insurance plan. Unfortunately our insurance does not cover immunizations or other well-child-care services. It would be a struggle for us to pay the costs of immunizing our children given that our out-of-pocket expenses for health care last year totalled almost $4,500. This amount included payments for premiums, well-child appointments, copayments, and deductibles.

Due to a high-risk pregnancy, my son Matthew was born prematurely in the state of Utah. Upon Matthew's birth and stabilization, we joined my husband who had already begun his studies at Michigan State University. My son's first health care provider in Michigan was a resident at the MSU Clinical Center specializing in neonatology. Because our doctor at the time was aware of our graduate student budget, he informed us about free immunizations administered at the Clinical Center the third Saturday of each month. As no appointments are taken, we have had to wait anywhere from thirty minutes to an hour for shots.

When we were expecting our second child and were concerned with the possibility of another high-risk pregnancy, our doctor at the MSU Clinical Center referred us to Dr. Hugh Culton, a partner in Lansing Pediatric Associates. We are pleased with the care that our children receive from Dr. Culton and we are confident that their early growth and development is being closely monitored by a regular health care provider.

We are aware of the costs of administering vaccines in a private practice. The doctor must cover the cost of vaccines purchased at market prices as well as his or her overhead. The total cost of immunization per child in the first eighteen months of life can run upward of $250. For us this amount is in addition to the cost of each well child appointment and our other health care costs for health insurance premiums, co-payments and deductibles.

Because we simply cannot afford this extra financial outlay, we continue to use the free immunization services of the MSU Clinical Center, after initially consulting with Dr. Culton. In the event that we cannot make it to the Clinical Center on the specified Saturday we take our children to the county health department. There we have waited with our healthy children for 45 minutes to an hour in a room filled with sick people, exposing our children to unnecessary health risks.

Dr. Culton keeps track of Matthew's and Beth Anne's growth and development and reminds us during their check-ups to see that they are immunized and that this information is recorded in their office medical histories. I am given no other reminder of when my children are due for their next series of shots.

Fortunately, I have been able to keep my children's immunizations current, though it has been difficult to arrange our busy schedule to fall within the operating hours of the Clinical Center or health department. While I have been able to keep my children's shots current, I have several friends who have not. All of them are well-educated people with private insurance. Like us, they too were referred by their physicians to the local health department for free immunizations. Problems due to their work schedules, illness or transportation have made visits to these free clinics

difficult. As a result their children's shots are not up-to-date. This creates a break in preventive health care. If cost had not been the factor that initially precluded their having received these shots during a regularly scheduled appointment with their primary care provider, their children would most likely be up-to-date on their immunizations and not at risk for disease.

Like all parents, Alan and I want to do our best to keep our children healthy. This includes providing them with proper preventive health care, the central component of which is the administration of regularly scheduled immunizations. I am here today to tell you that the current system can be improved by making immunizations more affordable to those parents who choose to take their children to a private physician. If immunizations can be provided by a child's primary care providers at a nominal cost for administering the vaccine, the net result will be that more children are fully immunized against infectious disease. The greater public good will be served when parents, the health industry, and government can work together in the important task of assuring preventive care for America's children.

Finally, I want to say I appreciate the support of the March of Dimes Birth Defects Foundation in helping me come to Washington, DC to testify before you. Thank you, again, for the opportunity to appear before you today.

PREPARED STATEMENT OF DAVID J. WILLIAMS

My name is David Williams and I am President and Chief Operating Officer of Connaught Laboratories, Inc. I appreciate the opportunity to provide Connaught's views on the proposed Comprehensive Child Immunization Act of 1993, as introduced by Senators Riegle and Kennedy. Connaught Laboratories, Inc. based in Swiftwater, Pennsylvania, is dedicated solely to the development and manufacture of vaccines and other biological products. Vaccines make up over 80% of our sales in the United States and 100% of the research we conduct is into new and improved vaccines. In our case, contrary to the suggestion made by Secretary Shalala in her testimony on this legislation on April 21, if an error were to be made in the pricing of our vaccine products, we could not make it up by charging more for our "other products."

We strongly support the Administration's objective of fully immunizing all children by age two. This country does an excellent job of immunizing our children by the time they enter school. We do it by five years of age, not because we do it free, but because we provide the motivation and incentives necessary for parents to have their children immunized. They must send their children to school, and their children must be immunized in order to attend. Having proven that it can be done by age five, we need to focus our attention and resources on programs that will work to get our children immunized by age two.

The Comprehensive Child Immunization Act of 1993 focuses on three areas in an attempt to solve the problem of low age-appropriate immunization rates in this country. They are:

1. Supply and Price—the universal purchase and distribution portions of the bill, which would, by our estimate require at least $1 billion a year of taxpayers' money to implement.
2. Follow-up—this is addressed by the provisions to develop and implement federally coordinated state tracking and registry systems which would require several hundred million dollars.
3. Motivation and Infrastructure—this area is being addressed by the continuation of outreach, education and infrastructure improvement programs already underway as part of other HHS initiatives. Little new money is being proposed for these most important activities.

We think the priority attached to, and allocation of resources devoted to each of these three areas are misdirected. Our recommendation is that universal purchase, which will do little to improve immunization rates and will jeopardize future vaccine development, *not* be included in final legislation.

We believe additional resources need to be invested in education, outreach, infrastructure improvements and tracking. Dramatic improvements could be realized in these areas at a substantially lower cost than universal purchase of all required vaccines.

In this testimony we will discuss:

—the scope of the immunization problem
—the real barriers to age appropriate immunization
—the solutions to these barriers
—data to prove that vaccine prices are not a barrier

—the universal purchase provisions of the legislation and their affect on the industry and the future of vaccine development, and
—the provisions dealing with the Vaccine Injury Compensation Program

DEFINING THE SCOPE OF THE PROBLEM

It is important to accurately define the problem in order to focus our resources most effectively. If we agree that taxpayers' money should be spent on solving the problem of low rates of age-appropriate immunization, we should focus our spending on activities, efforts and programs that will accomplish that objective. The United States does an excellent job of immunization, children who are about to enter school. According to the Centers for Disease Control and Prevention (CDC), over 96% of U.S. children are properly immunized by the time they reach school-age. if vaccine cost is not a barrier when a child is age five, why is it considered a barrier at age two?

A closer look at immunization levels for children younger than age two proves that a variety of factors other than cost are keeping children from vaccines. According to a CDC survey, less than half of our children are *fully immunized* by their second birthday. This does not paint a complete picture, however. Many of the remaining children included in these statistics have had some immunizations given in their first two years. It is clear that these *under*-immunized children are at far less risk of contracting disease than the *un*immunized. Moreover, a good portion of these children might be fully immunized shortly after their second birthday. The rest of the underimmunized could have their shots completed sooner through improved education and outreach efforts directed to their parents.

By overstating the scope of our problem and minimizing successes in private physicians' offices and public health clinics, precious dollars could be wasted that could be targeted to programs and activities that will benefit those who are in greatest need of our attention. It is the unimmunized children who are the ones most vulnerable to vaccine-preventable childhood diseases and their complications.

Approximately 50% of vaccines are purchased by the public sector at deeply discounted prices already provided by manufacturers. Because companies like Connaught have substantially discounted their vaccines to the public sector for many years, vaccines are readily available to children without charge. Yet according to the CDC, children who are eligible for free and low-cost vaccines have the lowest age-appropriate immunization rates. The point is that children are not being brought by their parents or guardians to be immunized.

Where does the most serious incidence of disease occur? It occurs in neighborhoods where most children are eligible for free vaccine and medical care. When serious outbreaks of measles and other diseases occurred during the late 1980s and early 1990s, minority children were disproportionately affected. Hispanic and African-American preschool children, particularly in urban areas, faced seven to nine times the risk of contracting measles than did Caucasian children. These children were, for the most part, eligible for Medicaid. Significantly, low-income, minority, inner-city children most often depend on acute-care clinics and other public-sector agencies for their primary healthcare and immunizations, with vaccines already available at no cost.

Secretary Shalala testified on April 21 that 60% of unimmunized children are from families whose incomes are above the poverty line. This figure seems to be derived from CDC figures estimating that 42% of all children above the poverty line are *fully* immunized by age two. We assume that the Secretary is using the inverse of this statistic. If this is so, then the 60% figure includes children, referred to earlier in our testimony, who have been immunized, but are missing perhaps only one shot to complete the schedule. Such children are not considered to be at significant risk for contracting these vaccine-preventable diseases. These children could have their schedules completed by simple cost-effective outreach efforts, such as reminders to parents and through the Administration's proposed tracking system. It also includes children who are Medicaid-eligible, and therefore eligible for free vaccine (all children under age six in families with incomes of 133% of poverty or less under current federal requirements, and some states include children in families up to 185% of poverty).

CDC data also show that more than enough vaccine is currently purchased by the public and private sectors each year to age-appropriately immunize every child in this country. In fact, with the exception of Hepatitis B which was recently added to the schedule, 110% of the vaccine needed to fully immunize every child by two is bought and distributed each year.

THE REAL BARRIERS TO PEDIATRIC IMMUNIZATION

A 1990 article in the *Journal of Health Care for Poor and Underserved* by Dr. Walter Orenstein et. al., described a survey of 54 immunization program managers on pediatric immunization barriers. The most frequently mentioned barriers were appointment-only systems (93%), insufficient staff (70%), insufficient clinic hours (56%) and requirements for prior physical examinations (56%). Similar conclusions are reached in a paper entitled "The Measles Epidemic: The Problems, Barriers and Recommendations," which was adopted by the National Vaccine Advisory Committee in 1991.

The findings in the bill also state that there has been a shift in immunizations from private physicians' offices to public clinics alleging "cost of privately purchased vaccine" as the reason. Since numerous studies document that the most comprehensive immunization services are provided in private physicians' offices—where children are more likely to have a "medical home"—Connaught strongly supports efforts to eliminate barriers in private physicians' offices. However, we know of only three sources of information on the issue of whether children are being "shifted" from private physicians offices to public clinics: CDC data, manufacturers' experience and an American Academy of Pediatrics (AAP) study completed in September, 1992.

CDC data and our own experience indicate that such a shift from the private to the public sector has not occurred. These sources are based on years of market experience, and reliable, verifiable data, while the AAP survey is based on a small sampling and anecdotal observations rather than hard evidence and data.

The CDC data go back more than 15 years and show no significant shift from the private to public sectors.

We do not believe that the conclusions of the AAP report can be supported by the study methodology. The AAP study consisted of a self-administered mail survey of 1,246 fellows of the Academy. The study is problematic for a variety of reasons, including an over-representation of residents, interns, and physicians involved in administrative and teaching positions. Survey respondents were also more likely to be employed in hospitals than the general pediatric physician population. Furthermore, the survey is based on the physicians' "perceived" recall of referrals over a ten-year period, and the questions related to the cost of vaccines did not adequately differentiate between the cost from the manufacturer and the cost to the patient, which includes physicians' fees. Because of the problems with the sample, the long timeframe for recalled perceptions and vague way key questions are phrased, we do not believe that this study can be applied to pediatric trends in general. In fact, Connaught supports the need for further studies of this nature with representative samples and multi-year tracking so any trends can be accurately detected.

To the extent that children are being referred to public clinics for immunization services, it is more than likely that they are being referred for all their healthcare needs. As noted above, a large segment of our unimmunized population is Medicaid-eligible. It is clear that physicians have been and continue to be disinclined to participate in Medicaid for a variety of reasons, including burdensome paperwork requirements and low reimbursement rates. Unless efforts to expand Medicaid coverage are coupled with efforts to convince private physicians to offer and deliver these services, there will be continued demand for increased resources for public health clinics and personnel. This is not a problem that is unique to the delivery of immunization services to children.

SOLUTIONS TO THE PROBLEMS

Given the size of the Federal deficit, there is a recognized need to focus scarce taxpayers' dollars on programs that will get children to vaccines. Solving the immunization problem will require that government, industry, parents and health professionals work together in a multi-faceted campaign. Study after study has documented some of the most important areas to address including:

1. Education for Parents and Healthcare Providers

Immunization, in ending the mass epidemics that once routinely killed or harmed our babies, may be a victim of its own success. Parents no longer see these preventable diseases as something to fear. We need educational programs that reinstitute—and even go beyond—the degree of appreciation of immunization that parents had in the past. Educational programs for healthcare providers on current vaccinations and appropriate contraindications are also important. These are the people who must educate the parents of today about current recommended vaccine schedules and the necessity of immunizing their children.

The CDC's Dr. Walter Orenstein said in his presentation to the National Vaccine Advisory Committee in March that the key factors in raising immunization rates

are motivation and accountability. He cited the experience of the state of Georgia in raising immunization rates over the past seven years without spending any new money. Immunization rates went from 35% to 75% by assigning seven public health workers full tine to travel around to the state's various public health clinics to maintain statistics, educate, exhort, supervise and generally make immunization a priority. This was accomplished by reallocating existing resources and focusing them on activities designed to raise immunization rates.

2. Innovative Delivery Mechanisms

We need to create a public health environment that welcomes parents and children, rather than keeps them away. To that end, we may have to go directly to them, rather than wait for them to come to us. There are a number of pilot programs having success in that area. The Children's Health Fund has created a clinic on wheels in New York, other cities and in rural areas; the National Immunization Campaign has a multi-faceted organizing and outreach effort on national and grassroots levels.

In addition, there are several government demonstration projects in New York, New Jersey and Illinois in which immunizations are combined with other services, such as food stamp purchase and welfare, to meet multiple needs simultaneously.

3. Infrastructure Improvements

We wholeheartedly support the Administration's intention to infuse more funds into the public health infrastructure. Such funds will directly address the most common barriers with initiatives to improve staffing, expand hours, and provide better transportation.

4. Immunization Tracking Systems

A national immunization registry to insure that each child's immunization record is automatically updated, wherever and whenever a vaccine is administered, is long overdue. A national immunization registry needs to be comprehensive and include the private sector, so that the immunization status of all children is accessible and updated as vaccines are administered. We firmly support the Administration's efforts to establish such a system and only wish it could be implemented sooner.

However, universal purchase is not a prerequisite for effective tracking systems. The Administration states that free vaccine is needed for tracking, i.e., doctors will get free vaccine in return for supplying tracking information to the CDC. The bill as currently drafted, envisions universal purchase and distribution of "free" vaccine as a stop-gap, temporary program. If "free" vaccine is the key to developing and operating a tracking system, what happens after the sunset clause takes effect and universal purchase stops?

In addition, as a condition of continuing to receive grant money under the bill, States are required to stop delivery of vaccine to providers who fail to collect and return tracking information. It is clear from this provision that the Administration believes that the distribution of free vaccine to providers will be adequate inducement to ensure that providers perform their "tracking" duties under the bill. It is just as likely to drive providers out of providing immunization services. Isn't this setting up another barrier to immunization? We think it *will* create another barrier to immunization, and that "free" vaccine will play little to no role in tracking.

Any tracking system must be designed with a minimal "hassle factor" so that doctors aren't driven away from delivering immunizations. Free vaccine will not be enough of an incentive to make providers participate in an overly burdensome information gathering system. Nor will lack of free vaccine dissuade providers from participating in a well developed, well run tracking program that not only does good for society but brings back the patients for follow-up services and treatment.

5. Eliminate Medicaid Obstacles

There are a variety of delivery systems for Medicaid-eligible children throughout the country. Some states have been successful in achieving high rates of immunization for Medicaid-eligible children, while others have not. In Connaught's opinion, the elimination of burdensome paperwork and the enhancement of fee schedules would eliminate much of the concern which has been misdirected at vaccine prices. Thus far, however, there has not been a comprehensive analysis of why some states are more successful at providing healthcare services to their Medicaid-eligible children. We applaud the Administration's intention to seek long-term funding to rebuild the infrastructure but believe that it will be necessary to include a careful analysis as noted above as the keystone for success. In addition, eligibility requirements should be standardized to establish accurate numbers of children who are receiving vaccines through Medicaid programs.

Connaught believes that Medicaid-eligible children should receive lower-priced vaccine and has a long-standing commitment to work on a state-by-state basis to accomplish that goal. To that end, we are offering states a Medicaid Reimbursement Program that seeks to provide public sector-priced vaccine to private physicians for their Medicaid-eligible patients in as efficient a way as possible. In addition, we believe that states should be able to buy vaccine for all Medicaid-eligible children at reduced prices.

Connaught also believes that all necessary childhood vaccines should be made accessible to the public sector at a discounted price and that appropriations should cover, for use by the medically indigent, all vaccines that are indicated for use and recommended by the Public Health Service's Immunization Practices Advisory Committee (ACIP) and by the Red Book Committee of the American Academy of Pediatrics.

6. Private Insurance Coverage for Immunizations

In the private sector, much needs to be done to encourage timely immunization. While many managed healthcare programs now cover immunizations, less than half of conventional, employment-based carriers do so. As a result, many underinsured patients must find their way to the public health sector for immunizations. The Commonwealth of Pennsylvania has addressed this issue by passing a law that requires all commercial group and individual policies that provide medical coverage for dependent children to provide first-dollar coverage for immunizations, including professional fees for administering the vaccines. Benefits for immunization services are exempt from deductible or dollar-limit provisions. We think this is a model approach that can have a significant impact on reducing the cost of immunization to the federal and state governments.

PRICE OF VACCINE NOT A BARRIER TO IMMUNIZATION

Any number of studies, including a report by HHS' National Vaccine Advisory Committee which has been studying immunizations for several years, have outlined the critical barriers to pediatric immunization. Cost is not one of them. In addition, leading health officials are convinced that universal purchase does not address the root of the problem. According to former U.S. Surgeon General C. Everett Hoop, M.D. ". . . the real problem is inadequate public education and access to, not availability of, vaccines." Dr. Francis Polumbo, a pediatrician who works in a large northwest Washington, D.C. practice where most patients have health insurance and well-educated parents, recently told the *Washington Post* that "Vaccines are available. The problem is that the kids are not available." A March 28, 1993 Bergen County (N.J.) Record article titled "Unused Vaccines" quotes Larry Lockhart, Associate Commissioner of the New Jersey Department of Human Services, as saying, "The vaccine cost is not an issue. It's putting doctors and pediatricians in the community and having a good system." If cost of vaccines were a barrier to immunization, it is clear that we would not have the success that we do at immunizing our children by age five.

VACCINE COSTS ARE REASONABLE

Since vaccine prices have been questioned, it is important to put these costs in perspective. Consider some common costs borne by parents of two year olds.

A common cost for parents of children under two is diapers. The amount of money spent on disposable diapers from birth to age two typically averages more than $1,400. This assumes seven changes per day at 28 cents per diaper for 730 days. For toys alone, American Demographics estimates that each U.S. family spends an average of $199 per year per child. Most children have at least one episode of otitis media by their third birthday, and more than one-third of all children have three or more episodes. Each episode results in at least one physician office visit and an antibiotic prescription. The typical office visit will cost $25 to $40, while a typical prescription will range from $10 to $12 (e.g., for Amoxicillin) to as much as $75 to $80 (e.g., for Augmentin® or Ceclor®), with the latter used more commonly in resistant strains and/or chronic cases. Additionally, decongestants and acetarninophen are commonly used. Thus, the typical direct cost to a family for each episode of otitis media ranges from $35 to $150. Indirect costs such as lost work time for parents can be significant, as well. Multiple or chronic episodes of otitis media are common, sometimes leading to complications and/or hospitalization.

By comparison the average price for all doses of vaccine charged by manufacturers (exclusive of excise taxes) to fully immunize a child by age two is $140.

EXAMINING IMMUNIZATION COSTS

Despite the fact that cost has not been shown to be a major barrier to immunization, vaccine prices have been the focus of much undue attention over the past few months. It might be useful, therefore to address this issue specifically.

There is no question about the cost-effectiveness of vaccines. As the President has noted, we save $10 for every $1 spent on vaccines. However, the reasons for increases in the cost of immunizations for children through age two have been misrepresented by the Administration. Eighty percent of the cost increase to fully immunize children by age two over the past decade is due to:

—Two new vaccines added to the immunization schedule to protect against Hepatitis B and Haemophilus influenzae type b (Hib), a leading cause of meningitis. The Hib vaccine alone is estimated to save $400 million per year in healthcare costs by virtually eliminating invasive Hib disease.

—A federal excise tax added to the price of certain pediatric vaccines to fund the National Vaccine Injury Compensation Program, a federal program designed to provide an orderly and swift mechanism to compensate those few who suffer unavoidable adverse reactions to the childhood vaccines that protect our children. The excise tax for all doses of vaccine required through school entry accounts for $32.84 of the cost increase over the past decade.

Vaccine production has become increasingly complex. It often takes ten to twelve years to bring a new product to the market, at a cost that is estimated by Brandeis' Gordon Public Policy Center to average $200 million. Increased costs to develop and manufacture vaccines account for the remaining price difference between 1982 and 1992. Manufacturing costs have risen because of:

—A proliferation of government regulations by FDA (CBER), OSHA and environmental agencies (Federal and State), such as EPA and DER. For example, the cost to manufacture our DTP vaccine rose nearly 500% since 1982. The overwhelming majority of this increase is due to government regulations and requirements. Our government does not permit vaccines to be manufactured the same way they were ten years ago. Nor should it, because changes in technology, and the related regulations have better ensured consistent quality. Substantial capital investments were required to comply with new government requirements and regulations, covering such areas as validation, aseptic techniques, and Good Laboratory and Clinical Practices.

At least 24 new regulations covering the manufacture or testing of vaccines were published between 1980 and 1992. Nine establishment license amendments were required to meet FDA-imposed modifications to facilities that manufacture vaccines. Nine product license amendments were required to meet FDA-imposed modifications to facilities that manufacture and distribute DTP vaccine.

—Sharply rising costs of insurance—which remains necessary for liability exposure that is not covered by the National Vaccine Injury Compensation Program. Due to an extremely litigious climate for vaccine manufacturers in the early 1980s, Connaught was unable to obtain adequate private insurance. To stay in business, we were forced to become primarily self-insured and our insurance premiums for the limited insurance we can purchase today have risen 750% since 1982. During the same period, deductibles rose by 2,000%.

Despite the tremendous increases in our costs, Connaught's prices in the public and private sectors have stabilized and for some products, dropped significantly. DTP public sector prices dropped from a high of $7.69 per dose in 1987—prior to enactment of the National Vaccine Injury Compensation Program—to $1.43 per dose in 1992 (exclusive of the $4.56 per dose federal excise tax). Private sector prices have followed practically in parallel.

A figure has been bandied about in public debate on the issue of vaccine cost. Many people have cited catalog prices, yet virtually no Connaught vaccine is sold at catalog price. In addition, the vaccine prices that have been widely publicized are often based on the highest catalog price. Less than one percent of vaccines are sold at this price. Even private physicians can take advantage of deep discounts if they buy in large enough quantity. In the private sector, the average price paid by the typical physician for all recommended doses of vaccines to school-entry is about $207 (this price includes the federal vaccine excise tax) versus the $240 so often referenced.

Since the cost of vaccines is a small part of complete immunization cost, asserting that families cannot afford to immunize their children because of the cost of the vaccine misrepresents the facts. Doctor's administration and office visit fees account for

a large percentage of immunization costs. For instance, a Medical Economics (October 19, 1992) article cited the average pediatricians' fee for administering a dose of DTP is $25, while the average selling price of a dose of DTP including the federal excise tax is $8.05. This does not include the office visit fee charged by most pediatricians. If a family cannot afford the cost of a dose of DTP, they certainly couldn't afford the associated provider fees.

COMPARISON OF COST TO IMMUNIZE AMONG DEVELOPED COUNTRIES

We have been asked to compare vaccine costs among major developed countries. Direct comparisons are difficult due to varying market structures, distribution mechanisms, recommended immunization schedules and manufacturers, as well as fluctuating currency exchange rates. However, based on the existing recommended vaccines and immunization schedule in the U.S., the total average cost for all vaccine doses in the U.S., Canada, U.K. and France in 1992 was about $140.00, with the U.S. falling somewhat below that average. For the U.S., this figure averages the costs in the private sector (about $175.00) and the public sector (about $80.00) (each accounts for about half the total market) and excludes the Federal excise tax, since the U.S. product liability situation is unique.

U.S. vaccine prices are certainly reasonable in comparison to other developed countries, as well as commonly purchased supplies for children under two.

WHY UNIVERSAL PURCHASE IS UNNECESSARY AND HARMFUL TO THE FUTURE OF VACCINE DEVELOPMENT

We can lean something from the experiences in the eleven states that have universal purchase programs. Many of these state programs have been in place for over twenty-five years, and the results have been mixed, but disappointing. The 1991 immunization rate for children two years and under was 49% in Idaho, 50% in Connecticut, 51% in Washington and 56% in South Dakota.

Although immunization levels in some universal purchase states are slightly better than the national average, according to the CDC's analysis this is likely due to other factors. For instance, New England states have few inner city areas and the preponderance of children are vaccinated by private physicians.

THE FUTURE OF VACCINE DEVELOPMENT

Universal purchase could jeopardize many of the promising new vaccines now in development. Connaught is a part of Pasteur Merieux Connaught (PMC), the world's largest supplier of vaccines, and undoubtedly has the world's largest annual investment in research and development directed toward vaccines. PMC has the most comprehensive product research portfolio which includes:

—Acellular /Component Pertussis for DTP
—AIDS (HIV)
—Combination vaccines—various of DTP, Hib, eIPV and/or Hepatitis B (in conjunction with Merck & Co., Inc.)
—Cytomegalovirus
—Dengue fever
—Hepatitis A
—Improved Influenza vaccine
—Improved Measles vaccine
—Improved Rabies vaccine
—Lyme Disease
—Malaria
—Meningococcal Conjugate Vaccines (Groups A, C, Y & W–135)
—Meningococcal Group B
—Otitis Media
—Parainfluenza Virus
—Pneumococcal Conjugate and Recombinant Vaccines
—Respiratory Syncitial Virus
—Typhoid
—Varicella (Chicken Pox)

A fundamental drawback of the universal purchase concept is that it does not account for the economic realities that influence manufacturers to remain in the vaccine market, adjust prices in accordance with the demands of competition, and pursue vaccine development and research. If most or all pediatric vaccines were purchased under federal or state contracts at bulk-purchase discounts, a company that did not win a contract award for a year or two would be unlikely to continue to invest in vaccine development or to a commitment of manufacturing resources.

Risks are extremely high and returns are too small to justify such investment. Thus, the result would likely be the elimination of manufacturers from the competitive market, which in turn would eliminate incentives for competitive price reduction and increase the risk of vaccine shortages. In addition, the prospect of insufficient returns on investment will discourage companies from engaging in vaccine research and development and may diminish efforts to improve existing or develop new vaccines. Vaccine prices reflect the ever increasing manufacturing costs but also the need to achieve reasonable returns on previous vaccine research and developments. We are on the verge of an explosion of new vaccine technology1 with new combination vaccines that protect against more diseases with fewer injections, and with many new products in the pipeline such as those against otitis media, the most common presenting complaint for pediatricians, and Respiratory Syncitial Virus infection, the leading cause of childhood hospitalization in this country.

The costs of otitis media alone are very substantial. An estimated 18.6 million pediatric physician office visits in the U.S. were for otitis media in 1992, second only to routine well-baby/child health check-ups and immunizations as a reason for physician office visits. Using the 18.6 million office visits and an average direct cost of $75 per visit, yields total direct out-patient costs of $1.4 billion in 1992. Hospitalization and surgical procedures add substantially to that amount.

In 1990, total direct and indirect costs of otitis media were estimated to be at least $3.5 billions including $300–$600 million in lost work time for parents of children with otitis media. An effective otitis media vaccine would have a dramatically beneficial economic impact.

Unfortunately, the universal purchase program proposed in the Child Immunization Act, may put an end to this kind of research and hurt considerably companies like Connaught—which focuses almost entirely on vaccines—in the process.

A closer examination of pricing and market conditions under a universal purchase system underlines the danger of this approach. Why it is doubtful that the Government as single purchaser would negotiate a price that supports the industry's R&D efforts and why would such an approach transform the industry?

While in theory it might be possible for the Government to negotiate prices that support R&D at current levels, in practice the whole notion behind universal purchase is to lower prices; and therefore one would have to argue that one can get the same or improved productivity from R&D activity by lowering prices, i.e., that there is a causal link between government price setting and improved innovation.

The industry today operates within a framework of investment risk and reward. Its major investments are: (i) research and development; (ii) plant and equipment; and (iii) operating costs. The risks are primarily technical, i.e., the risk that its research and development strategies will fail, and competitor/market-based, i.e., the risk that new products, even when launched, will not be successful versus the competition. The financial rewards to the manufacturers for making these investments and taking these risks are defined by price and volume mix of products which are sold in both the public and private markets.

Universal purchase, as proposed in the legislation, fundamentally changes the current investment risk-reward equation. The likely effects of these changes will be to transform the basis of competition in the industry, and possibly, industry structure itself. Given its relative negotiating power, with no floor to the price that the Government could demand, hypothetically the Government could thrust prices on existing suppliers which would result in the orderly liquidation of the industry as no manufacturer made further investments.

This, however, is an unlikely scenario. As envisioned in the Universal Purchase proposal, the Government intends to regulate price on a cost-plus basis. In the long-run, however, cost-plus regulation results in higher prices.

While in the short-run, there might be the possibility of reduced prices, in the long-run, replacing the investment-risk-reward environment with a cost-plus environment will result in higher prices. The effect of MCI and Sprint on long-distance telephone pricing versus the pricing in the previously regulated AT&T monopoly is among the best examples of this economic reality.

The destructive effects of universal purchase do not stop, however, with the destruction of price competition for existing products. The second major casualty of this policy is almost certainly all interim combination products, which protect against more diseases with fewer injections, and possibly all future new or improved pediatric vaccines.

Consider the data that will be used by the Secretary for negotiating prices. Virtually all of the data are related to the historical cost of the vaccine in question. In addition, there are to be "profit levels sufficient to encourage research and development of new or improved vaccines." What does this mean? The profits that encourage investment are not the profits on existing vaccines, but *the expected profits*

on the future new or improved vaccines! Manufacturers today try to measure market demand for potential new products and go forward with research and development efforts if they think the demand, although not "universal," is sufficient to warrant the risk of making the investment. But, the Government has set itself up as a monopsonist (the sole purchaser). In the universal purchase, cost-plus environment, manufacturers will have to ask the Government, and since the Government is the only purchaser, the Government will need to give a clear indication as to its intent. Anything less than contractual commitments will not be sufficient to ensure the current level of research and development activity.

Effectively, then, the Government has not only put existing vaccines in a universal purchase, cost-plus environment, but it also has put funding of the development of all future vaccines into the same cost-plus environment. As to the efficiency and effectiveness of such an environment, as compared to a private sector-driven investment, risk-reward environment, one need look no further much of the history of defense procurement.

It certainly is a concern that the unpredictable federal budgets in some years could seriously jeopardize vaccine supply and distribution across the country, as well as all vaccine research and development. The vulnerability of federal vaccine programs became apparent by the recent lapse of provisions of the National Vaccine Injury Compensation Program in October, 1992, which leaves children who are injured in the unlikely event of an adverse vaccine reaction unprotected.

Unless the Government will guarantee, in advance, the existence of a market, development of new and improved vaccines will be curtailed. This means that the Government will have to settle the current medical community debate over which combination products to produce, and may have to enter into contractual commitments as to which other new vaccines it would like developed and produced, and by which companies.

THE NATIONAL CHILDHOOD VACCINE INJURY COMPENSATION ACT: A CALL TO ACTION

The provisions of the bill dealing with the The National Childhood Vaccine Injury Compensation Act must be addressed immediately. If necessary, they should be separated from the bill and be acted upon separately. The Vaccine Injury Compensation Act has helped play a major role in stabilizing both the supply and price of vaccines. Products liability has been a potent determinant of the cost of—and attitudes about—vaccines in the last ten years. It not only significantly increased the overall cost of immunization, it also created a climate of fear among parents and led to an informed consent process that is complicated land often frightening.

Ultimately, working closely with physicians, manufacturers and parents, the federal government enacted this program that went into effect in 1988 and was funded by the federal excise tax placed on each dose of vaccine. Unfortunately, the excise tax expired on December 31, 1992 along with authorization to use previously collected taxes to pay for claims based on vaccinations administered after October 1, 1992. Immediate legislative attention is needed to reinstate both the Act and the excise tax and amend the program to cover new vaccines.

While we agree with the recommended changes regarding extending the time for decision-making under the program, the addition of new vaccines to the Injury Table and the simplification of the Vaccine Information Materials, we have some suggestions regarding modification of the excise tax provisions. First the bill would reinstate the excise taxes retroactively to April 1, 1993. Apart from the legal/Constitutional questions raised by this provision, it is also unfair. It is illegal for manufacturers to start collecting these taxes until a law is enacted. If the Secretary determines that the Trust Fund is in any danger of being depleted as a result of the current "hiatus" in collection of the excise taxes, she can recommend that the excise taxes be increased as necessary after the amendments are signed into law.

In addition, the bill fails to amend the Internal Revenue Code to provide for excise taxes for the vaccines that will be newly added to the Injury Table. Connaught has recommended that any vaccine added to the Injury Table have an excise tax applied, even if only a nominal amount in order to maintain the solvency of the Compensation Fund. If new vaccines are added to the Injury Table without an excise tax to pay for the awards that might be granted as a result of injuries caused by the new vaccines, the Compensation Program may be placed in financial jeopardy. The excise tax amounts should be subject to amendment administratively by the Secretary under procedures similar to those for making changes to and additions of vaccines to the Injury Table.

SUMMARY

We applaud the Clinton Administration's intention to ultimately include childhood immunizations as part of a basic benefits package under Health Care Reform. However, using scarce taxpayers' dollars for a universal purchase program as a stopgap measure with no proven utility in raising immunization levels will have serious long-term repercussions that could jeopardize our entire industry.

Connaught and other companies must be allowed to continue to be responsible to the children in the U.S. The only way we can do this is to continue developing new and improved vaccines. Unfortunately, it will be the children and their parents who will suffer as the pace of new vaccine development is slowed or brought to a standstill by those who want to regulate prices of existing vaccines and the development of new and improved vaccines unnecessarily through a government procurement process.

We hope the members of this Committee will look beyond universal purchase towards legislation that will, in fact, break down the barriers to pediatric immunization and achieve the goal, which we all share, of full immunization of every child by two. We believe the focus of the legislation and the taxpayer dollars that will pay for this initiative should be trained on education and outreach and efforts to improve the delivery infrastructure and to develop tracking systems that can be linked nationwide. We will do our part to hold down costs to state governments in their efforts to fulfill their responsibilities to the indigent and we are hopeful that childhood immunization will be made a part of any basic healthcare package that is developed in connection with the healthcare reform process. Thank you.

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